

1 FEDERAL TRADE COMMISSION

2 I N D E X (PUBLIC RECORD)

3

4 WITNESS: DIRECT CROSS REDIRECT RECROSS

5 Herman 2483 (SP) 2538

6 Rule 2569 (SP) 2583

7

8 EXHIBITS FOR ID IN EVID

9 Commission

10 None

11 Schering

12 Numbers 1222

13 through 1266 2462

14 Upsher

15 Numbers 1500

16 through 1542 2464

17

18 OTHER EXHIBITS REFERENCED PAGE

19 Commission

20 CX 458 2513

21 CX 459 2514

22 CX 462 2514

23 CX 464 2544

24 CX 465 2519

25 CX 468 2521

For The Record, Inc.
 Waldorf, Maryland
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1	Commission	
2	CX 469	2523
3	CX 470	2525
4	CX 472	2491
5	CX 473	2526
6	CX 474	2494
7	CX 478	2538
8	CX 479	2539
9	CX 480	2539
10	CX 491	2489
11	CX 1673	2549
12	Schering	
13	SPX 73	2495
14	SPX 74	2496
15	SPX 76	2503
16	SPX 77	2498
17	SPX 94	2519
18	SPX 550	2495
19	SPX 680	2486
20	SPX 1204	2496
21	SPX 1198	2513
22	Upsher	
23	None	
24		
25		

For The Record, Inc.
Waldorf, Maryland
(301) 870-8025

1 FEDERAL TRADE COMMISSION

2

3 In the Matter of:)

4 SCHERING-PLOUGH CORPORATION,)

5 a corporation,)

6 and)

7 UPSHER-SMITH LABORATORIES,) File No. D09297

8 a corporation,)

9 and)

10 AMERICAN HOME PRODUCTS,)

11 a corporation.)

12 -----)

13

14 Thursday, February 7, 2002

15 12:00 p.m.

16 TRIAL VOLUME 11

17 PART 1

18 PUBLIC RECORD

19 BEFORE THE HONORABLE D. MICHAEL CHAPPELL

20 Administrative Law Judge

21 Federal Trade Commission

22 600 Pennsylvania Avenue, N.W.

23 Washington, D.C.

24

25 Reported by: Susanne Bergling, RMR

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1 P R O C E E D I N G S

2 - - - - -

3 JUDGE CHAPPELL: Good afternoon, everyone.

4 ALL COUNSEL: Good afternoon, Your Honor.

5 JUDGE CHAPPELL: Ms. Bokat, call your next
6 witness, please.

7 MS. BOKAT: Our next witness will be put on
8 through readings from excerpts previously designated.
9 The witness' name is James Audibert. We had read at a
10 previous session from his investigational hearing
11 transcript. Our remaining reading is from his
12 deposition. Mr. Ginsburg and Ms. Apori will be
13 handling those readings again today.

14 JUDGE CHAPPELL: Okay, thank you.

15 MR. GINSBURG: As Ms. Bokat indicated, we will
16 be reading from the deposition of Mr. James Audibert
17 from October 24th, 2001. At that time, it is my
18 understanding that he was the senior director for
19 commercial optimization in the Schering-Plough Research
20 Institute.

21 Page 34, line 3:

22 "QUESTION: Is a pharmacokinetic study, is
23 something like that -- is that required to get
24 an NDA?

25 "ANSWER: I'm not sure if it's always

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1 required.

2 "QUESTION: You just don't know?

3 "ANSWER: I don't know if it's a -- if it's
4 a flat out absolute requirement or not. I
5 just don't know.

6 "QUESTION: Are you aware of situations
7 where it was required to get an NDA?

8 "ANSWER: Again, I don't know if it was
9 required. I know they're done. I don't know
10 whether they're done because the people -- you
11 clearly have to be able to profile the
12 behavior of your product in terms of how it's
13 absorbed and what have you. What the specific
14 regulatory requirement is as to how to do
15 that, I really don't know."

16 MR. GINSBURG: Page 82, line 8.

17 "Audibert Deposition Exhibit Number 6,
18 Memory, Russo to Distribution, 3/26/97, was
19 marked for identification.

20 "BY MR. EISENSTAT:

21 "QUESTION: Mr. Audibert, I'd like you to
22 look over this document and tell me if you
23 recognize it.

24 "ANSWER: Yes, I've seen this before.

25 "QUESTION: When was the last time you saw

1 this?

2 "ANSWER: Yesterday.

3 "QUESTION: Do you recall seeing it before
4 yesterday?

5 "ANSWER: No, I cannot say I specifically
6 remember seeing this before yesterday.

7 "QUESTION: This memo is addressed to
8 Distribution. Do you see that?

9 "ANSWER: Yes.

10 "QUESTION: And the distribution list is on
11 the second page. Do you see that?

12 "ANSWER: Yes.

13 "QUESTION: Is your name on the
14 distribution list?

15 "ANSWER: Yes."

16 MR. GINSBURG: Page 84, line 2:

17 "QUESTION: Okay. Do you see in the first
18 paragraph it says, " 'We are in the process of
19 evaluating the commercial opportunity for the
20 sustained niacin product from Kos
21 Pharmaceuticals called Niaspan. Currently we
22 are doing a technical evaluation within SPRI
23 and have initiated an external review of the
24 support materials provided by Kos. Our first
25 review is being performed by the lipid

1 advisory group that attended our recent 58235
2 meetings in New York.'

3 "Do you see that section?

4 "ANSWER: Yes.

5 "QUESTION: First of all, again, what's
6 SPRI?

7 "ANSWER: Schering-Plough Research
8 Institute.

9 "QUESTION: And do you know what a
10 technical evaluation within SPRI means?

11 "ANSWER: I'm not sure there's a definitive
12 definition, but I'm assuming what it means is
13 having the people within SPRI look over what
14 information they have.

15 "QUESTION: Are the people within SPRI, are
16 they trained medical people?

17 "ANSWER: Some are; some aren't.

18 "QUESTION: What kind of skills would
19 they -- would they have?

20 "ANSWER: Oh, it could be people -- SPRI
21 includes a large group of scientists, anywhere
22 from clinicians to people who are
23 toxicologists, people who are actually
24 involved with formulations. So, you have all
25 types of scientific disciplines within our

1 research organization.

2 "QUESTION: Okay. Where it says, 'The
3 first review is being performed by the lipid
4 advisory group that attended the recent 28235
5 meetings,' what were the 58235 meetings?

6 "ANSWER: I believe what Ray is talking
7 about there is we -- 58235 is the Schering
8 number for ezetimibe, which is our
9 cholesterol-lowering agent that was in
10 development at that time and is still in
11 development, and we had some advisory groups
12 with experts in the cholesterol-lowering area
13 to actually talk about the opportunities with
14 that particular product, how was cholesterol
15 being managed today, how it's going to be
16 managed in the future.

17 "QUESTION: Who would be included in the
18 lipid advisory group?

19 "ANSWER: It would be outside clinicians.

20 "QUESTION: Would that be doctors?

21 "ANSWER: Yes.

22 "QUESTION: Did you attend 58235 meetings
23 in New York?

24 "ANSWER: Yes."

25 MR. GINSBURG: Page 86, line 8:

1 "QUESTION: The word 'technical
2 evaluation,' would that include a review of
3 the efficacy of the product?

4 "ANSWER: I guess it would depend upon what
5 information the company gave us.

6 "QUESTION: If there was data there to
7 review efficacy, would they review that?

8 "ANSWER: Probably.

9 "QUESTION: For a product like this, would
10 they -- would the review include a review of
11 the liver toxicity and the flushing issues,
12 the safety issues we talked about?

13 "ANSWER: Again, if that information were
14 supplied, it could be reviewed by them."

15 MR. GINSBURG: Page 88, line 18:

16 "QUESTION: Okay. I direct your attention
17 to the third numbered point under the line
18 that says, 'For this opportunity to be viable
19 for SGP, a number of issues must be resolved,'
20 and that third number point says, 'Due
21 diligence validation of issues regarding,'
22 then there's patent status, finalized
23 labeling, manufacturing capabilities and
24 product liability.

25 "Do you see that?

1 "ANSWER: Yes.

2 "QUESTION: When you were doing your
3 commercial assessment of Niacor-SR,
4 Upsher-Smith's product, did you do any due
5 diligence regarding patent status?

6 "ANSWER: Did I?

7 "QUESTION: Yes.

8 "ANSWER: No.

9 "QUESTION: Do you know if anybody did any
10 due diligence regarding patent status?

11 "ANSWER: I don't know if anybody did.

12 "QUESTION: When you were doing your
13 commercial assessment of Niacor-SR, did you do
14 any due diligence validation with respect to
15 finalized labeling?

16 "ANSWER: No.

17 "QUESTION: Do you know if anybody did?

18 "ANSWER: I don't know.

19 "QUESTION: When you were doing --

20 "MR. NIELDS: Are you assuming that there
21 was a possibility of doing finalized labeling
22 on Niacor?

23 "MR. EISENSTAT: I'm not assuming anything.
24 I'm merely asking the man what he did.

25 "QUESTION: When you were doing your due

1 diligence validation -- excuse me, when you
2 were doing your commercial assessment of
3 Niacor-SR, did you do any due diligence
4 validation of manufacturing capabilities?

5 "ANSWER: Did I? No.

6 "QUESTION: Do you know if anybody did?

7 "ANSWER: I don't know. I don't know that.

8 "MR. NIELDS: Are you assuming there that
9 Upsher-Smith was going to do the
10 manufacturing?

11 "MR. EISENSTAT:

12 "QUESTION: When you were doing your
13 commercial assessment of Niacor-SR, did you do
14 any due diligence validation of product
15 liability?

16 "ANSWER: What does that mean?

17 "QUESTION: I don't know.

18 "ANSWER: I don't know what that -- I don't
19 know what that means."

20 MR. GINSBURG: Page 90, line 24:

21 "QUESTION: When you were doing your
22 commercial assessment of Niacor-SR, did you do
23 any due diligence work with respect to any
24 information from Upsher-Smith?

25 "ANSWER: Me personally you're talking

1 about?

2 "QUESTION: Yes.

3 "ANSWER: I did due diligence in the sense
4 of I carefully reviewed the information that
5 Upsher-Smith had provided us about the
6 product.

7 "QUESTION: Did you go any -- beyond what
8 they had provided you about the product?

9 "ANSWER: No."

10 MR. GINSBURG: Page 91, line 18:

11 "QUESTION: And it goes on to read, 'We
12 assume that the safety profile, levels of
13 liver toxicity, side effects and approved
14 indications would be consistent with the
15 proposed labeling included in the Kos package.
16 We would, of course, subject any deal to this
17 criteria.'

18 "Do you see that?

19 "ANSWER: Yes.

20 "QUESTION: Did you ever see any proposed
21 labeling of Upsher-Smith Niacor-SR product
22 when you were doing your commercial assessment
23 of that product?

24 "ANSWER: No.

25 "QUESTION: Do you know if there was any

1 proposed labeling of that product?

2 "ANSWER: I'm not aware of any."

3 MR. GINSBURG: Page 92, line 14:

4 "QUESTION: The next sentences in that
5 section reads, 'We will need to independently
6 assess this product's worldwide potential.
7 This product has begun and preliminary results
8 should be available in the next two weeks with
9 a broader assessment to follow.'

10 "Do you know what he's talking about there?

11 "ANSWER: Not specifically.

12 "QUESTION: Do you know if he's talking
13 about your survey that you sent out to the
14 subsidiaries of Schering-Plough?

15 "ANSWER: It could very well be that, but I
16 don't know specifically what he was referring
17 to here.

18 "QUESTION: Do you know if you were still
19 working on the Niaspan product or the Niaspan
20 license possibilities when this was sent out
21 in March of 1997?

22 "ANSWER: I don't know."

23 MR. GINSBURG: Page 93, line 10:

24 "QUESTION: Do you know of anyone else
25 besides yourself who was gathering information

1 on the Niaspan product's worldwide potential?

2 "ANSWER: No.

3 "QUESTION: The last paragraph of the
4 document begins, 'Our next step is to meet
5 with Kos on April 9th and identify the open
6 issues/opportunities and share with them the
7 value SGP could bring to this project,' and it
8 goes on from that.

9 "Do you see that paragraph?

10 "ANSWER: Yes.

11 "QUESTION: And a little further down in
12 that paragraph, there's a line that says,
13 'Karin Gast, Jim Audibert, Toni DeMola and I
14 will continue to work with Kos and will set up
15 our next meeting in the next two weeks.'

16 "Do you see that?

17 "ANSWER: Yes.

18 "QUESTION: Does that refresh your
19 recollection at all as to whether you were
20 still working on this project at March 26th?

21 "ANSWER: Again, I don't remember. I don't
22 remember specifically, you know, could very
23 well be. The that Ray still thinks I'm still
24 working on it doesn't necessarily mean I'm
25 still actively involved in the process.

1 "What was the date on this memo here?

2 "QUESTION: Which --

3 "ANSWER: That was -- that was March 14th
4 that I sent out to the subs. So, I don't
5 remember at this point in time whether I was
6 still --

7 "QUESTION: Yeah, let me just go over that
8 for you to make you follow the sequence.

9 "ANSWER: Yeah.

10 "QUESTION: Do you have Exhibit 3 in front
11 of you?

12 "ANSWER: Yes.

13 "QUESTION: And that's the contact report,
14 right?

15 "ANSWER: Yes.

16 "QUESTION: And that's the -- the contact
17 date was March 13th?

18 "ANSWER: Correct.

19 "QUESTION: And then you sent out your memo
20 to the subs on March 14th. Is that correct?

21 "ANSWER: Yes.

22 "QUESTION: And then on March 26th, Ray
23 sent out this memo saying we will need to
24 independently assess the product's worldwide
25 potential. Do you see that?

1 "ANSWER: Right."

2 MR. GINSBURG: Page 95, line 16:

3 "QUESTION: And Ray's memo, though, does
4 have you listed both in distribution and in
5 the text as working -- continuing to work with
6 Kos. Is that right?

7 "ANSWER: That's what it says.

8 "QUESTION: When you're working on a
9 project with other people at Schering, such as
10 this project on the Niaspan product, and you
11 stop working, do you tell your superiors?

12 "ANSWER: No, no, no.

13 "QUESTION: You just stop working and don't
14 tell anybody?

15 "ANSWER: That may very well happen.

16 "QUESTION: Are you aware, though, that the
17 other members of your team, Karin Gast and Ray
18 Russo, continued to work with Kos?

19 "ANSWER: Vaguely, yeah, aware of it,
20 yeah."

21 MR. GINSBURG: Page 96, line 14:

22 "MR. EISENSTAT: I'd like to have marked as
23 Audibert Exhibit 7 a document bearing the
24 numbers SH 002746 through SP 002749."

25 MR. GINSBURG: Page 98, line 9:

1 "QUESTION: This contact report appears to
2 be regarding a meeting that was held between
3 Schering and Kos. Do you have any
4 recollection of attending this meeting?

5 "ANSWER: I did not attend this meeting.

6 "QUESTION: You're sure you did not attend
7 this meeting?

8 "ANSWER: Yes, very sure.

9 "QUESTION: Does this confirm in your mind,
10 though, that, in fact, Karin Gast and Ray
11 Russo were continuing to work on the Niaspan
12 product after you stopped?

13 "ANSWER: It would appear, but I -- I can't
14 tell you that. It would appear that they went
15 there on April 9th, but I don't have a clear
16 date in my mind when I sort of disengaged from
17 the whole Niaspan project. So, I don't know
18 where this falls in relationship to that -- to
19 when I was pulling back.

20 "QUESTION: Do you recall doing anything
21 else with respect to the Niaspan product --
22 project?

23 "ANSWER: No."

24 MR. GINSBURG: Page 100, line 23:

25 "QUESTION: When did you first learn that

1 Schering was considering taking out a license
2 for Niacor-SR? Not when you were first asked
3 to do your commercial assessment, but when
4 were you first told that Schering was
5 considering taking out a license for
6 Niacor-SR?

7 "ANSWER: It had to be after I did my
8 assessment, but when exactly, I -- I don't
9 remember."

10 MR. GINSBURG: Page 102, line 22:

11 "QUESTION: During the time you were
12 working on your commercial assessment of
13 Niacor-SR -- first of all, do you recall about
14 how long it was you worked on that?

15 "ANSWER: I don't remember the exact
16 length, but it was a number of days, but I
17 don't remember the exact number of days that I
18 worked on it.

19 "QUESTION: Today, do you recall if there
20 was any sense of urgency in getting your
21 commercial assessment done?

22 "ANSWER: Yes, because virtually everything
23 that Mr. Lauda asked me to do had a sense of
24 urgency behind it.

25 "QUESTION: During the time you were

1 working on your commercial assessment of
2 Niacor-SR, do you recall if you had any
3 conversations or any communications with Mr.
4 Kapur?

5 "ANSWER: While I was doing my assessments?

6 "QUESTION: Yes.

7 "ANSWER: Not that I remember, no.

8 "QUESTION: All right. During the time you
9 were doing your assessment -- your commercial
10 assessment of Niacor-SR, do you recall having
11 any communications with Mr. Wasserstein?

12 "ANSWER: No.

13 "QUESTION: During the time you were doing
14 your commercial assessment of Niacor-SR, do
15 you recall having any conversations with
16 anybody else at Schering other than Mr. Lauda?

17 "ANSWER: No.

18 "QUESTION: When you were doing your
19 commercial assessment of Niacor-SR, did you
20 talk to Karin Gast?

21 "ANSWER: About the assessment or just did
22 I talk to Karin Gast?

23 "QUESTION: Well, let's just start, did you
24 talk to Karin Gast?

25 "ANSWER: I don't remember talking to her.

1 "QUESTION: Do you remember talking to her
2 about Niacor-SR during the time you were doing
3 your commercial assessment?

4 "ANSWER: No.

5 "QUESTION: Didn't you think it would be
6 useful to talk to Karin Gast since she had
7 worked on the Niaspan product longer than you
8 did and might have additional information?

9 "ANSWER: No.

10 "QUESTION: You didn't think she could have
11 additional information that would be helpful
12 to you?

13 "ANSWER: No.

14 "QUESTION: How about Mr. Russo, did you
15 talk to him while you were working on your
16 commercial assessment of Niacor-SR?

17 "ANSWER: Not that I'm aware of, not that I
18 remember, no.

19 "QUESTION: Do you think there's a
20 possibility that he would have had information
21 that would have been useful to you in doing
22 your commercial assessment Niacor-SR?

23 "ANSWER: No.

24 "QUESTION: How about people in the SPRI,
25 the Schering-Plough Research Institute, did

1 you talk to any person there while you were
2 doing your commercial assessment of Niacor-SR?

3 "ANSWER: No.

4 "QUESTION: Did you see any need to?

5 "ANSWER: No.

6 "QUESTION: When you were assigned to do
7 your commercial assessment of Niacor-SR, were
8 you given any instructions regarding talking
9 to other people about your project?

10 "ANSWER: No.

11 "QUESTION: No one told you you couldn't
12 talk to these other people?

13 "ANSWER: No.

14 "QUESTION: What do you recall you were
15 asked to do with respect to Niacor-SR?

16 "ANSWER: To generate a sales forecast for
17 the product based on the information that was
18 provided.

19 "QUESTION: And this was Mr. Lauda who gave
20 you these instructions?

21 "ANSWER: Yes, yes.

22 "QUESTION: Were you told to limit yourself
23 to the information that was provided?

24 "ANSWER: No, not that I -- I don't
25 remember that."

1 MR. GINSBURG: Page 109, line 18:

2 "QUESTION: You said that Mr. Lauda had
3 instructed you to do a sales forecast. Is
4 that correct?

5 "ANSWER: Yes.

6 "QUESTION: For the Niacor-SR product?

7 "ANSWER: Yes.

8 "QUESTION: And did he instruct you to do
9 anything else besides a sales forecast?

10 "ANSWER: I know at the end I did a profit
11 and loss assessment, so I'm assuming he asked
12 for that also."

13 MR. GINSBURG: Page 110, line 16:

14 "QUESTION: Let's start there, when you
15 were asked to do the assessment.

16 "ANSWER: Yeah, I was asked to do an
17 assessment.

18 "QUESTION: Were you asked to do anything
19 else during that time period?

20 "ANSWER: Regarding Niacor?

21 "QUESTION: Regarding Niacor.

22 "ANSWER: No.

23 "QUESTION: Not by anybody?

24 "ANSWER: No.

25 "QUESTION: Did anybody ever ask you to do

1 any due diligence investigation beyond the
2 papers that were given to you with respect to
3 Niacor?

4 "MR. NIELDS: Asked and answered.
5 Objection, asked and answered. You can
6 answer.

7 "THE WITNESS: Okay, repeat the question.

8 "MR. EISENSTAT: Can you read back the
9 question, please?

10 "QUESTION: Did anybody ever ask you to do
11 any due diligence investigation beyond the
12 papers that were given to you with respect to
13 Niacor?

14 "THE WITNESS: You're talking about while I
15 was doing the assessment?

16 "QUESTION: While you were doing the
17 assessment.

18 "ANSWER: No.

19 "QUESTION: Do you know whether a license
20 agreement was ever signed between Schering and
21 Upsher-Smith?

22 "ANSWER: Yes.

23 "QUESTION: And was an agreement signed?

24 "ANSWER: Yes.

25 "QUESTION: Before that agreement was

1 signed, were you asked to do anything else
2 with respect to Niacor-SR besides the sales
3 projection and the profit and loss?

4 "ANSWER: No.

5 "QUESTION: Did you do anything with
6 respect to Niacor-SR prior to the signing of
7 the agreement between Schering and
8 Upsher-Smith besides the sales projection and
9 the profit and loss assessment?

10 "ANSWER: Not that I remember.

11 "QUESTION: Do you know who was the sponsor
12 of the license agreement between Upsher-Smith
13 and Schering?

14 "MR. NIELDS: Do you understand that
15 question?

16 "THE WITNESS: What do you mean by
17 'sponsor'?

18 "MR. EISENSTAT:

19 "QUESTION: Are you familiar with the term
20 'sponsor' as it's used in Schering to talk
21 about licensing agreements?

22 "ANSWER: The term is used sometimes, but
23 it -- it's an -- no, I'm not exactly sure how
24 the term would be used.

25 "MR. EISENSTAT: Let me have marked as

1 Audibert Exhibit 8 a document bearing the
2 numbers SP 018744 through SP 018755.

3 "QUESTION: Mr. Audibert, I'd you just to
4 look over the document over and see if you've
5 ever seen this before.

6 "ANSWER: I do not believe I've ever seen
7 this before.

8 "QUESTION: Are you familiar with the
9 procedures by which the management at Schering
10 puts together proposals for licenses and gets
11 appropriate approvals within the corporation?

12 "ANSWER: No.

13 "QUESTION: Did you ever work on a proposal
14 for the Schering-Upsher-Smith license?

15 "ANSWER: No.

16 "QUESTION: Did you ever see a proposal for
17 the Schering-Upsher-Smith license?

18 "ANSWER: I have to say I don't remember
19 seeing one.

20 "MR. EISENSTAT: I'd like to have marked as
21 Audibert Exhibit 9 a document bearing the
22 number SP 1600040 through SP 1600047, and let
23 me state for the record that the document was
24 previously marked as Exhibit 1 at Mr.
25 Audibert's investigational hearing on the 21st

1 of September, year 2000.

2 "QUESTION: Mr. Audibert, I'd ask you to
3 look this document over and see if you
4 recognize it.

5 "ANSWER: Yes, I recognize it.

6 "QUESTION: And what is the document?

7 "ANSWER: This was my write-up on the
8 assessment of Niacor, the sales forecast.

9 "QUESTION: Could you turn to the last page
10 of the document, the document bearing number
11 SP 1600047. Do you have that page in front of
12 you?

13 "ANSWER: Yes.

14 "QUESTION: Does this page show your sales
15 forecast for Niacor-SR?

16 "ANSWER: Yes.

17 "QUESTION: Could you explain for the
18 record how you went about making these
19 assessments?

20 "ANSWER: Well, to make a sales forecast,
21 the first thing I would look at it is what is
22 the -- what is the anticipated size of the
23 cholesterol-lowering market in the territories
24 we're talking about, and because of all the
25 work I was -- had been doing with ezetimibe

1 and the market preparation activity, I had
2 spent a lot of time on clearly looking at what
3 is the current market size, what is the future
4 market of cholesterol. So, the first thing is
5 to establish just what's the size of the
6 market and overall.

7 "Then what I would do is looking at the
8 information that's provided to me in the
9 package, knowing what I know about the
10 marketplace in terms of what types of products
11 are out there, what type of efficacy they
12 have, what type of safety, what type of
13 pricing they have, I would -- again, based on
14 a lot of experience, knowing the profile of
15 this -- of the Niacor product, saying what's a
16 reasonable price that I think we could get for
17 the product based on this profile, then what's
18 a reasonable market share based on the
19 product's profile, and then it just becomes
20 merely a matter of math.

21 "If the market is \$126 million and I think
22 it can be -- you know, we can get a one and a
23 half percent -- excuse me, if the market is
24 whatever the market is and we get 1.5 percent,
25 it comes out, for example, to 1.26 -- \$126

1 million in 2002. It's rounded off, but
2 maybe -- yeah, it's rounded off. For example,
3 on the previous page, I had projected that the
4 cholesterol market, ex-U.S./Mexico/Canada,
5 would be \$8.4 billion in 2002, and if you get
6 1.5 percent, then that was that \$126 million.

7 "QUESTION: When you did your analysis, did
8 you estimate the number of prescriptions that
9 Schering would actually get in making these
10 sales projections?

11 "ANSWER: No.

12 "QUESTION: Did you estimate -- in getting
13 your sales estimates, did you estimate the
14 percentage of prescriptions written for
15 cholesterol-lowering that Schering would get
16 with this product?

17 "ANSWER: No.

18 "QUESTION: Do you know what percentage of
19 the prescriptions written for cholesterol
20 outside of the United States, Canada and
21 Mexico your sales forecasts represent?

22 "ANSWER: I'm sorry, repeat the question.

23 "QUESTION: Do you know what percentage of
24 the prescriptions written for cholesterol
25 outside of the U.S., Canada and Mexico your

1 sales estimates represent?

2 "ANSWER: No. Outside of the U.S., we
3 traditionally don't look at prescriptions,
4 because there are no good databases in the
5 international markets regarding the
6 prescription -- the number of prescriptions,
7 the size of prescriptions and what have you.

8 "QUESTION: You said given what you
9 determined was a reasonable price -- and
10 correct me if I'm wrong, but I think you said
11 you looked for a reasonable price, and then
12 you looked at what's a reasonable market share
13 based on your experience and the profile of
14 the product and that price. Is that right?

15 "ANSWER: Um-hum, yes.

16 "QUESTION: Let's turn to SP 1600044. Do
17 you see the top section, the section marked
18 Niacor-SR?

19 "ANSWER: Yes.

20 "QUESTION: And do you see the first
21 paragraph that begins, 'Niacor-SR is a
22 patented sustained-release niacin product
23 designed to be administered at bedtime'?

24 "ANSWER: Yes.

25 "QUESTION: Why did you say that Niacor-SR

1 is a patented, sustained-release niacin
2 product designed to be administered at
3 bedtime?

4 "ANSWER: The -- I mentioned it's patented
5 because it provided some -- based on the
6 information that the company had provided us,
7 it appeared that they had a patent. Designed
8 to be administered at bedtime, I believe based
9 on the information that I had read, not only
10 the information within the one dossier, but
11 then in some protocol design sheets for future
12 studies they were planning, it appeared that
13 they were going -- their goal was to have the
14 product be administered at bedtime.

15 "QUESTION: When you wrote this, was Niacor
16 a sustained-release niacin product designed to
17 be administered at bedtime?

18 "ANSWER: No, I think that was a mistake on
19 my part. It had not at that time -- because
20 the clinical studies had been on a twice-a-day
21 product.

22 "QUESTION: Was Niaspan a once-a-day
23 product designed to be administered at
24 bedtime?

25 "ANSWER: I believe so, yes.

1 "QUESTION: Does being a once-a-day
2 product -- a once-a-day sustained-release
3 niacin product designed to be administered at
4 bedtime give a competitive advantage over a
5 product that's administered twice a day,
6 everything else being equal?

7 "ANSWER: It would be a minor advantage.

8 "QUESTION: And why do you say 'minor
9 advantage'?

10 "ANSWER: Any time you can have a product
11 administered once a day versus twice a day,
12 that is an advantage in terms of patient
13 compliance, but I would offer that it's a
14 small advantage."

15 MR. GINSBURG: Page 122, line 3:

16 "MR. EISENSTAT: Let me have marked as
17 Audibert Exhibit 10 a document bearing the
18 number SP 1600061 through SP 1600112. Again,
19 let me state for the record that this has
20 previously been marked as Audibert Exhibit 2
21 in Mr. Audibert's investigational hearing on
22 the 21st of September, year 2000."

23 MR. GINSBURG: Page 123, line 5:

24 "QUESTION: What I'd -- let's turn back to
25 page SP 16000062. Do you have that page in

1 front of you?

2 "ANSWER: Yes.

3 "QUESTION: And the bottom of the page
4 has -- it says, 'Niacor-SR Patents.'

5 "Do you see that?

6 "ANSWER: Yes.

7 "QUESTION: And the first patent listed
8 there is the Evenstad patent. Do you see
9 that?

10 "ANSWER: Yes.

11 "QUESTION: Did the Evenstad patent, to
12 your understanding, provide any patent
13 protection in Europe for Niacor-SR?

14 "ANSWER: I wasn't aware.

15 "QUESTION: Could you turn to the next
16 page, look at the top of the page where it
17 says, 'Niacor-SR Evenstad Patent.'

18 "Do you see that?

19 "ANSWER: Yes.

20 "QUESTION: Can you tell there if the
21 patent provides any protection in Europe?

22 "ANSWER: It doesn't mention Europe.

23 "QUESTION: So, does the patent provide any
24 patent protection in Europe?

25 "ANSWER: Not that I'm aware of.

1 "QUESTION: And the next section on that
2 same page, SP 1600063, lists the O'Neill
3 patent. Do you see that?

4 "ANSWER: Yes.

5 "QUESTION: Could you tell if at the time
6 you were considering this the O'Neill patent
7 provided any patent protection in Europe?

8 "ANSWER: I can't tell by this whether it
9 provides any patent protection.

10 "QUESTION: Can you turn to the next page?
11 It's SP 1600064. Do you see the top section,
12 'Niacor-SR O'Neill Patent'?

13 "ANSWER: Yes.

14 "QUESTION: Does the O'Neill patent provide
15 any patent protection in Europe?

16 "ANSWER: It just says right now it's been
17 filed and status is pending.

18 "QUESTION: Does that provide you any
19 patent protection in Europe?

20 "ANSWER: No."

21 MR. GINSBURG: Page 124, line 25:

22 "QUESTION: Do you recall if there's
23 anything in this document that suggested that
24 Upsher-Smith was going to move to a
25 once-a-day, at-bedtime formulation of

1 Niacor-SR?

2 "ANSWER: In this particular document?

3 "QUESTION: Yes.

4 "ANSWER: No.

5 "QUESTION: There is nothing?

6 "ANSWER: Not that I remember seeing in

7 here.

8 "MR. EISENSTAT: I'd like to have marked as
9 Audibert Exhibit 11 a document bearing the
10 number SP 1600113 through SP 1600140. And
11 again, let me just state for the record that
12 this was previously introduced at Mr.
13 Audibert's investigational hearing on
14 September 21st, year 2000."

15 MR. GINSBURG: Page 125, line 22:

16 "QUESTION: Did you have this before you
17 did your sales projections?

18 "ANSWER: Yes.

19 "QUESTION: I direct your attention to the
20 page marked SP 1600115. Do you have that page
21 in front of you?

22 "ANSWER: Yes.

23 "QUESTION: Let me direct your attention to
24 the sentence that starts at the very end of
25 the page, where it says, 'There may be some

1 benefit in once-a-day bedtime dosing since
2 this correlates with cholesterol production in
3 the liver.'

4 "Do you see that?

5 "ANSWER: Yes.

6 "QUESTION: Do you agree with that
7 statement?

8 "ANSWER: I'm not -- again, I'm not aware
9 of any specific information that supports that
10 theory.

11 "QUESTION: Do you know of any information
12 that is contrary to that theory?

13 "MR. NIELDS: Do you mean with the word
14 'may' in that sentence?

15 "THE WITNESS: I don't know of anybody
16 who's disproved this, but I am not aware of
17 anybody who's proved it either.

18 "QUESTION: Okay. Was there anything in
19 this document you recall that suggested to you
20 that Upsher-Smith was going to formulate their
21 product for a once-a-day, at-bedtime product?

22 "ANSWER: Yes.

23 "QUESTION: Could you show me where that
24 is?

25 "ANSWER: If one goes to the second page,

1 which is 0014, one will see that there's -- at
2 the top of the page, you have -- the paragraph
3 right below that, 'The dosing schedules are as
4 follows,' there's three different dosing
5 schedules, one, two and three, and you will
6 see both dosing schedule two and dosing
7 schedule three, the final dosing schedule, in
8 those two arms of the studies, there's 15
9 milligrams qhs, which means every bedtime, for
10 18 weeks.

11 "QUESTION: Qhs means every bedtime?

12 "ANSWER: Bedtime, that's correct.

13 "QUESTION: What does qhs stand for?

14 "ANSWER: Q means -- I don't remember the
15 Latin, but q means every, and hs means
16 bedtime.

17 "QUESTION: Is dosing at bedtime the same
18 time as dosing with the evening meal?

19 "ANSWER: No.

20 "QUESTION: Let me direct your attention
21 then to SP 1600116. The last sentence at the
22 top paragraph says, 'In order to determine the
23 most efficacious dosing schedule, patients
24 will be dosed once or twice daily with meals
25 in this study.'

1 "Is that consistent with dosing once --

2 "ANSWER: Okay, I'm sorry --

3 "QUESTION: -- a day at bedtime?

4 "ANSWER: -- where are you?

5 "QUESTION: SP 1600116.

6 "ANSWER: Yes.

7 "QUESTION: At the top of the page, above
8 Objective, the last sentence above Objective
9 says, 'In order to determine the most
10 efficacious dosing schedule, patients will be
11 dosed once or twice daily with meals in this
12 study.'

13 "ANSWER: And what's your question?

14 "QUESTION: Is that consistent with dosing
15 once at bedtime?

16 "ANSWER: It could be.

17 "QUESTION: Dosing with an evening meal is
18 the same with dosing at bedtime?

19 "ANSWER: It doesn't say that it's with an
20 evening meal.

21 "QUESTION: Okay, let's look at SP 1600117.
22 Do you see the Dosing Regimen section at the
23 top?

24 "ANSWER: Yep.

25 "QUESTION: Do you see the sentence that

1 says, 'Dosing will be twice daily with meals
2 or a single dose with the evening meal,
3 depending on randomization'?

4 "ANSWER: Yes.

5 "QUESTION: Is that consistent with dosing
6 at bedtime?

7 "ANSWER: Unless the patient goes to bed
8 right after their evening meal, I'd say no.

9 "QUESTION: And, in fact, this doesn't say
10 anything here about dosing at bedtime, does
11 it?

12 "MR. NIELDS: What doesn't?

13 "MR. EISENSTAT: The Dosing Regimen
14 section.

15 "MR. NIELDS: This whole Dosing Regimen
16 section doesn't say that?

17 "MR. EISENSTAT: 3.2, Dosing Regimen.

18 "MR. NIELDS: Oh, 3.2?

19 "THE WITNESS: Yeah, there clearly is a
20 discrepancy here between what is said here in
21 terms of dosing with evening meal and when I
22 went to pharmacy school, and I think it stands
23 today, hs means bedtime.

24 "QUESTION: Okay. So, what's in the text
25 is not consistent with the way you read the

1 front page -- the front.

2 "ANSWER: That's correct."

3 MR. GINSBURG: Page 129, line 22:

4 "QUESTION: Did you notice this discrepancy
5 when you first reviewed this material and were
6 working on your sales projection?

7 "ANSWER: No."

8 MR. GINSBURG: Page 130, line 8:

9 "QUESTION: Could you turn to the page
10 marked SP 1600044 once again. I think you
11 said that the first statement, 'Niacor-SR is a
12 patented, sustained-release niacin product
13 designed to be administered at bedtime,' was
14 incorrect as of the time this was written. Is
15 that right?

16 "ANSWER: That's correct."

17 MR. GINSBURG: Page 137, line 3:

18 "QUESTION: How about in terms of comparing
19 their attractiveness in the market, would
20 looking at the indications be a way to compare
21 two products' attractiveness in the market?

22 "ANSWER: Yes."

23 MR. GINSBURG: Page 140, line 14:

24 "QUESTION: Okay. When were you planning
25 to prepare the dossiers for European

1 registration of Niacor-SR?

2 "ANSWER: We would begin -- my plan was
3 once they started to assemble their dossiers,
4 we would in parallel start to do some
5 preparation of -- at the same time.

6 "QUESTION: Okay. Had you had any
7 conversations with Upsher-Smith with respect
8 to their plans on when they expected to begin
9 preparing their filing of their NDA?

10 "ANSWER: No.

11 "QUESTION: When were you assuming that
12 they would begin preparing their NDA?

13 "ANSWER: I didn't have an assumption of
14 when they were going to begin preparing. My
15 assumption was that they would be filing by
16 the end of 1997.

17 "QUESTION: So, they would have had to
18 begin preparing it sometime before then?

19 "ANSWER: Yes.

20 "QUESTION: And when they started gathering
21 the stuff, you expected to begin putting
22 together your dossiers for Europe?

23 "ANSWER: Yes.

24 "QUESTION: Did you do any review of
25 communications between Upsher-Smith and the

1 FDA before you prepared your sales estimates
2 for Niacor-SR?

3 "ANSWER: No.

4 "QUESTION: Do you know if when Schering
5 licenses a drug from another company, they
6 typically check communications between that
7 company and the FDA if the product has not
8 been approved yet?

9 "ANSWER: I'm not sure what's typically
10 done, because I'm not involved in many of the
11 deals."

12 MR. GINSBURG: Page 146, line 7:

13 "QUESTION: Would it have any meaning to
14 you in terms of the likelihood that
15 Upsher-Smith would meet that end of 1997
16 deadline to file their NDA if they had not yet
17 done a PK study that was acceptable to the
18 FDA?

19 "ANSWER: At that time -- it's hard for me
20 to say without knowing the specifics.

21 "QUESTION: What specifics would you have
22 to know?

23 "ANSWER: Well, PK -- PK studies can be
24 done very quickly. So, without knowing what
25 specific type of PK study the FDA wanted, and

1 based on the information they were targeting
2 an end of '97 filing, I'm doing my assessment
3 in June of '97, what I don't know is, you
4 know, it's not -- some PK studies can be
5 literally 12 healthy adult nonsmoking males,
6 you can do a study in -- I mean, literally
7 days. So, it's hard to say, without knowing
8 the specific requirements that the FDA is
9 asking for, to know whether or not that study
10 could be done to have in time for filing at
11 the end of the year."

12 MR. GINSBURG: Page 147, line 7:

13 "QUESTION: Did you know how, when you did
14 your assessment, that Upsher-Smith had not
15 performed a PK study at that time that was
16 satisfactory to the FDA?

17 "ANSWER: I'm sorry, repeat the question.

18 "QUESTION: When you did your sales
19 projections, your sales analysis, at that
20 time, did you know that Upsher-Smith had not
21 done a PK study that was acceptable to the
22 FDA?

23 "ANSWER: No, I did not know that."

24 MR. GINSBURG: Page 149, line 23:

25 "QUESTION: Let's go back to Exhibit 9,

1 page SP 1600045.

2 "ANSWER: I'm sorry -- oh, okay, 0045 you
3 said?

4 "QUESTION: Yes. Do you have that in front
5 of you?

6 "ANSWER: Yes.

7 "QUESTION: The second point under the
8 Sales Projection title are, 'Product
9 reimbursed in most major markets.'

10 "Do you see that?

11 "ANSWER: Yes.

12 "QUESTION: Is that what we talked about
13 earlier today, where the Government would
14 reimburse some or all of the cost of the drug
15 for people who got a prescription?

16 "ANSWER: Yes.

17 "QUESTION: And you assumed the product
18 would be reimbursed in most markets then for
19 your analysis?

20 "ANSWER: Yes."

21 MR. GINSBURG: Page 151, line 11:

22 "QUESTION: So, did you assume that your
23 product would be reimbursed in Italy?

24 "ANSWER: I didn't do a specific, you know,
25 country-by-country assessment, but most major

1 markets, there's five -- you know, we use five
2 major markets in Europe, the UK, France,
3 Germany, Spain and Italy. I didn't go through
4 country by country and make a, you know, sales
5 assessment.

6 "QUESTION: Well, when you say 'most major
7 markets,' are you referring to some portion of
8 these five major markets?

9 "ANSWER: Yeah, I -- again, I just made an
10 assumption that the product -- in most major
11 markets, that the product would be reimbursed.

12 "QUESTION: Well, when you say 'most,'
13 though, what were you thinking specifically
14 with respect to these five? Were you assuming
15 that you would be reimbursed in all five of
16 these major markets?

17 "ANSWER: Yes. Yes, based on the profile
18 of the product, what I saw as a real need in
19 the marketplace in terms of the health
20 authorities looking for newer agents to treat
21 their patients -- to treat their population
22 with, to address the cholesterol, which
23 everybody recognizes is a real need. I'm
24 assuming that quite frankly all the major
25 markets would reimburse for the product.

1 "QUESTION: Did you do any survey of your
2 international subsidiaries to find out if
3 there were sustained-release niacin products
4 on the market in those countries?

5 "ANSWER: Other than that original memo
6 that I sent out to the subsidiaries back in I
7 guess March, no.

8 "QUESTION: Did you go back and check that
9 and see what the results were before you did
10 your analysis of Niacor-SR?

11 "ANSWER: No."

12 MR. GINSBURG: Page 182, line 18:

13 "QUESTION: Do you know what the term
14 'recurrent myocardial infarction' means?

15 "ANSWER: Where are you?

16 "QUESTION: That's not on the document.

17 "ANSWER: Recurrent?

18 "QUESTION: Recurrent myocardial
19 infarction.

20 "ANSWER: Recurrent myocardial infarction?
21 No.

22 "QUESTION: Do you know whether Niacor-SR
23 was going to have an indication for reduction
24 of recurrent myocardial infarction in patients
25 with a history of myocardial infarction?

1 "ANSWER: I wasn't assuming that.

2 "QUESTION: Do you know if there are
3 sustained-release niacin products that have an
4 indication for a reduction of recurrent
5 myocardial infarction in patients with a
6 history of myocardial infarction?

7 "ANSWER: I don't remember now what
8 Niaspan's, you know, labeling is, so I don't
9 know.

10 "QUESTION: Do you know what 'reduction of
11 recurrent myocardial infarction in patients
12 with a history of myocardial infarction'
13 means?

14 "ANSWER: What's -- what do they call it,
15 recurrent?

16 "QUESTION: Recurrent.

17 "ANSWER: Recurrent. I'm not sure -- I
18 suspect what they're talking about there is
19 reduce the incidence of patients getting
20 subsequent heart attack who have had a first
21 heart attack.

22 "QUESTION: Do you know whether, everything
23 else being equal, a sustained-release niacin
24 product that had an indication for reduction
25 of recurrent myocardial infarction in patients

1 with a history of myocardial infarction would
2 have a competitive advantage in the
3 marketplace over a sustained-release niacin
4 product that did not have that indication?

5 "ANSWER: If the -- if a sustained-release
6 niacin product got that claim based on a study
7 that was done, a long-term morbidity and
8 mortality study, that was done with that
9 specific product so as to achieve that claim,
10 and another product did not have that claim
11 because they had not done that long-term
12 morbidity and mortality study, yes, I would
13 say there would be a competitive disadvantage.
14 I'm not aware of any sustained-release niacin
15 product that's done a long-term morbidity and
16 mortality study to get that claim.

17 "QUESTION: Are you aware of any
18 sustained-release niacin product that has that
19 claim without having done a long-term study?

20 "ANSWER: I believe -- and again, I don't
21 know for sure, but I believe Niaspan has some
22 type of claim, but it's my clear understanding
23 that that claim, if, in fact, they do have
24 that, is based on the vast knowledge and
25 database of niacin and on some specific niacin

1 studies, not on the Kos product.

2 "QUESTION: Okay. So, everything else
3 being equal, in your view, would the
4 indication that Kos has for its claim on
5 myocardial infarction, would that give it a
6 competitive advantage over other
7 sustained-release niacin products in the
8 marketplace?

9 "ANSWER: If -- I'm assuming that the Kos
10 claim is what I would call a class labeling
11 claim, okay, i.e., they have gotten that data
12 not based on a clinical study that they've
13 done, because I have to say based on my
14 understanding of what Niaspan was doing, I
15 mean, these studies are usually five years in
16 duration, \$200 million in cost, and I don't
17 believe Kos spent that type of time and money
18 on that product.

19 "So, I would offer if Kos was successful in
20 convincing a regulatory agency, regardless of
21 where that occurs, that their product should
22 have that labeling, then any other
23 sustained-release niacin should be successful
24 in getting that same type of labeling, because
25 that's what I would call 'class labeling.'

1 "QUESTION: So, a Niacor-SR could have
2 gotten that same labeling?

3 "ANSWER: They should be, yes, because to
4 the best of my knowledge, Niaspan did not do
5 the job -- do the study. They only referred
6 to the vast database on niacin, and that
7 data -- that same database should apply to
8 another sustained-release niacin product.

9 "QUESTION: Do you know what progressive
10 arthrosclerotic disease is? A R T H R O S C L
11 E R O T I C.

12 "ANSWER: Arthrosclerotic disease -- what
13 was the first word?

14 "QUESTION: Progressive arthrosclerotic
15 disease is?

16 "ANSWER: Well, arthrosclerosis is the
17 concept of the hardening of the arteries, as
18 we think of it in lay terms, so that means,
19 you know, progressively getting worse.

20 "QUESTION: Do you know if Niacor-SR would
21 have had an indication for slowing progressive
22 arthrosclerotic disease in patients with a
23 history of coronary artery disease when used
24 in a combination with bile-binding resins?

25 "ANSWER: I don't know whether they have

1 that labeling or not.

2 "QUESTION: Well, Niacor-SR never had any
3 labeling --

4 "ANSWER: Oh, I'm sorry, you're asking
5 Niacor or Niaspan?

6 "QUESTION: Niacor.

7 "ANSWER: Well, Niacor, they don't have any
8 labeling, per se, or I'm not aware that they
9 have gotten any labeling.

10 "QUESTION: Are you aware of whether they
11 were planning to have that indication?

12 "ANSWER: I'm not aware of that.

13 "QUESTION: Do you know if there are any
14 sustained-release niacin products that have
15 that indication for slowing progressive
16 arthrosclerotic disease in patients with a
17 history of coronary artery disease when used
18 in combination with bile-binding resins?

19 "ANSWER: I'm not aware.

20 "QUESTION: Do you know whether, everything
21 else being equal, a sustained-release niacin
22 product that had an indication for slowing
23 progressive arthrosclerotic disease in
24 patients with a history of coronary artery
25 disease when used in combination with

1 bile-binding resins would have a competitive
2 advantage in the marketplace over a
3 sustained-release niacin product that did not
4 have that indication?

5 "ANSWER: Well, as I said before, if a
6 particular product in the marketplace had that
7 specific indication, because that particular
8 product had done the clinical work to get that
9 particular claim, and another company, another
10 product, did not do that particular work to
11 get that claim, clearly having that claim
12 would be a competitive advantage.

13 "However, as I mentioned in the case of
14 myocardial infarction, if, in fact, that claim
15 is based on literature and more of a class
16 labeling rather than specific labeling as an
17 outcome of clinical studies done with that
18 particular product, then I would see it as not
19 a competitive advantage, because the second
20 company should be able to get that same
21 labeling as the first company based on
22 literature. It's not done based on that
23 specific product.

24 "QUESTION: And if for whatever reason the
25 second company could not get that same

1 labeling, would that second company be at a
2 competitive disadvantage then in the
3 marketplace?

4 "ANSWER: If they could not convince the
5 regulatory authorities that they should have
6 the same class labeling as the first product,
7 yeah, they would be at a disadvantage."

8 MR. GINSBURG: Page 193, line 19:

9 "QUESTION: Turning back to Exhibit 9, page
10 SP 1600045, the next bullet point is, 'Niacor
11 is the only SR niacin with that labeling for
12 the first three years on the market.'

13 "Do you see that?

14 "ANSWER: Yes.

15 "QUESTION: Why did you assume that Niacor
16 would be the only SR niacin with that labeling
17 for the first three years on the market?

18 "ANSWER: Because I -- based on my limited
19 involvement with Niaspan, it appeared that
20 they were going to focus on the U.S. market.
21 I wasn't aware that Niaspan had a partner, so
22 therefore, I didn't see Niaspan going into the
23 European market unless they had entered into
24 some kind of international deal, which I
25 hadn't heard of, and therefore, we had a

1 particular expertise, because we're well
2 established in Europe, that we could move
3 quickly with a dossier, where unless Kos had a
4 partner, because Kos is the only other product
5 out there, a sustained-release niacin, as I
6 see it, I would -- I was not aware that Kos
7 had an international partner, and based on my
8 limited involvement with Kos, I'm not sure
9 they were going to have a partner based on the
10 way they treated their potential partners in
11 terms of deals or what have you.

12 "QUESTION: There are other companies out
13 there besides Schering that Kos could partner
14 with?

15 "ANSWER: Yes.

16 "QUESTION: There are European companies
17 they could partner with?

18 "ANSWER: Sure.

19 "QUESTION: And there are other American
20 companies they could partner with?

21 "ANSWER: Sure.

22 "QUESTION: And Kos was ahead of
23 Upsher-Smith in terms of the approval
24 process -- the approval progress for their
25 NDA. Isn't that right?

1 "ANSWER: That's correct.

2 "QUESTION: And do you know when
3 Upsher-Smith -- excuse me, do you know when
4 Kos got their NDA?

5 "ANSWER: I want to say mid-'97, but I'm
6 not exactly sure when.

7 "QUESTION: And in mid-'97, Upsher-Smith
8 hadn't even filed yet. Is that right?

9 "ANSWER: That's correct.

10 "QUESTION: Could we turn back to Exhibit
11 5, which bears the number FTC 0001405.

12 "ANSWER: Okay, product assessment, okay,
13 this one, it says --

14 "QUESTION: It's the one that attaches your
15 sustained-release niacin questionnaire.

16 "ANSWER: Yes, okay.

17 "QUESTION: Do you see the last paragraph
18 there where it talks about the product? The
19 next to the last product -- excuse me, the
20 next to the last paragraph on the first page,
21 where it says, 'The product offered to us.'

22 "Do you see that?

23 "ANSWER: Yes.

24 "QUESTION: And it says -- goes on to say,
25 'The product will be a prescription product in

1 the U.S. labeled for the treatment of
2 hyperlipidemia and will be available at 375,
3 500, 750 and 1000 milligram tablets.'

4 "Do you see that?

5 "ANSWER: Yes.

6 "QUESTION: And do you see it goes on to
7 say, 'It could be on the European market by
8 mid-1998'?

9 "ANSWER: That's correct.

10 "QUESTION: Do you know why you wrote to
11 these people and said it could be on the
12 European market by mid-1998?

13 "ANSWER: Well, my thinking being that if
14 we did a deal with Kos, we could be --
15 probably be on the market in mid-1998.

16 "QUESTION: If someone else did a deal with
17 Kos, could they be on the market that quickly?

18 "ANSWER: Yeah."

19 MR. GINSBURG: Page 202, line 6:

20 "MR. EISENSTAT: Let me have marked as
21 Audibert Exhibit 15 Respondent Schering-Plough
22 Corporation's Statement of the Case involving
23 Schering and Upsher-Smith.

24 "QUESTION: Mr. Audibert, have you ever
25 seen what's been marked as Audibert Exhibit 15

1 before?

2 "ANSWER: I don't believe I've ever seen
3 this.

4 "QUESTION: Okay. Let's turn to the second
5 page of the document, and there's a small
6 paragraph in the center of the page that says,
7 'Two Schering officials, who were not made
8 aware of the patent lawsuit, evaluated the
9 proposed Niacor-SR license and concluded that
10 it was worth more to Schering than the price
11 Upsher was asking.'

12 "Do you see that sentence?

13 "ANSWER: Yes.

14 "QUESTION: Did you evaluate the proposed
15 Niacor-SR license and conclude that it was
16 worth more to Schering than the price Upsher
17 was asking?

18 "ANSWER: No."

19 MR. GINSBURG: Page 220, line 10:

20 "QUESTION: The document continues in the
21 next paragraph, 'Mr. Audibert, who was unaware
22 of the patent litigation, reviewed the
23 information concerning Upsher's clinical
24 trials and did a written financial assessment
25 of the proposed Niacor-SR license.'

1 "Did you do a written financial assessment
2 of that proposed Niacor-SR license?

3 "ANSWER: I guess it depends upon what one
4 means by a 'written financial assessment.' I
5 would interpret -- I would call my --

6 "MR. NIELDS: Exhibit 5.

7 "THE WITNESS: -- yeah, Exhibit 5 -- no,
8 Exhibit 9.

9 "MR. NIELDS: I'm sorry.

10 "THE WITNESS: Yes. Exhibit 9, if that's
11 what you're calling a written financial -- I
12 would call that a written financial
13 assessment.

14 "QUESTION: Would you call that a written
15 financial assessment of the license?

16 "ANSWER: Yes -- oh, I'm sorry, of the
17 license? Wait a second, what was the
18 question? Okay, let's go back to the
19 question. What is specifically --

20 "And did a written -- ah, of the
21 proposed -- I -- okay, did a written financial
22 assessment of the proposed Niacor-SR license.
23 I guess it -- it really depends on upon what
24 one defines as the proposed Niacor-SR license.

25 "QUESTION: Did you ever see the proposed

1 Niacor-SR license?

2 "ANSWER: No -- the license, you're meaning
3 the deal that the companies were discussing
4 evidently?

5 "QUESTION: Yes.

6 "ANSWER: No certainly -- I might have seen
7 it later, but certainly when I was doing my
8 assessment I did not.

9 "QUESTION: Okay. So, at the time, could
10 you have done a financial assessment of the
11 proposed license if you had never seen the
12 license?

13 "ANSWER: Again, I guess it depends upon
14 how one defines the license.

15 "QUESTION: Well, did you know what the
16 terms of the license were?

17 "ANSWER: No.

18 "QUESTION: Isn't it fair to say that what
19 you did was an assessment of the commercial
20 opportunity?

21 "ANSWER: For the Niacor-SR product.

22 "QUESTION: Right. Yes, for the --

23 "ANSWER: If you want to call the
24 opportunity is what was the value, what was my
25 assessment of the commercial value of the

1 Niacor-SR product.

2 "QUESTION: Right.

3 "ANSWER: Yes, that's what I did.

4 "QUESTION: That's what you did?

5 "ANSWER: That's correct.

6 "QUESTION: And you never went through the
7 license terms and did an evaluation of any
8 specific license terms at all?

9 "ANSWER: No, I did not."

10 MR. GINSBURG: Page 224, line 7:

11 "QUESTION: Just a couple more questions.

12 "Has Schering ever entered into a license
13 to license a product from another company
14 where you were the only one who reviewed
15 clinical data?

16 "ANSWER: Where I was the only one?

17 "QUESTION: Yes.

18 "ANSWER: Not that I'm aware of.

19 "QUESTION: Do you know of anyone else
20 besides yourself who reviewed clinical data on
21 the Niacor-SR product?

22 "ANSWER: No.

23 "QUESTION: Are you aware of any case where
24 Schering's entered into a license to license a
25 product from another company where the

1 Schering research group, SPRI, has not been
2 involved in reviewing clinical data?

3 "ANSWER: I'm not intimately involved with
4 the licensing agreements in all of the areas,
5 so the answer to that is no."

6 MR. GINSBURG: That's all, Your Honor, we have
7 from Mr. Audibert's deposition. Thank you.

8 JUDGE CHAPPELL: Schering?

9 MS. SHORES: We do have some counter-readings,
10 Your Honor, and Mr. Raofield and Mr. Koons will be
11 handling those on behalf of Schering.

12 JUDGE CHAPPELL: Okay, you may proceed.

13 MR. RAOFIELD: Page 35, line 18, complaint
14 counsel questioning the witness:

15 "QUESTION: What do you recall about the
16 phone conversations you had with --
17 participated in with Kos?

18 "ANSWER: Well, I think the points that I
19 remember the most is, one, they were very
20 excited about the product. They thought the
21 product would really address some of the
22 shortcomings of niacin, which had been why
23 people don't use niacin to treat cholesterol,
24 which is the side effects.

25 "They were very excited and they felt that

1 their particular product had a much better
2 safety profile, that is, a side effect
3 profile, than immediate-release niacin, and
4 they were very excited about it, and I
5 remember very specifically they were very
6 unrealistic in terms of what their
7 expectations were from us in terms of
8 co-promotion activity."

9 MR. RAOFIELD: Page 49, line 11, complaint
10 counsel questioning the witness:

11 "QUESTION: Do you recall any discussion --
12 at this telephone conversation between
13 yourself, Mr. Russo and Ms. Gast and Mr. Bell
14 and Mr. Heatherman, do you recall any
15 discussion of the marketing of Niaspan outside
16 the United States?

17 "ANSWER: I -- I don't, again, remember
18 specific discussion, and I'm not sure if it
19 was here or I believe one other conference --
20 one other conference call I participated in,
21 but I -- I vaguely remember some discussion
22 about this, but I -- but what I guess I
23 remember more importantly is that European or
24 non-U.S. registration, marketing was not a
25 high priority for Kos at this point in time.

1 "QUESTION: Do you recall any discussion as
2 to why non-U.S. marketing was not a high
3 priority for Kos at this time?

4 "ANSWER: Again, I have some -- a vague
5 recollection of the -- either Dan Bell or Dave
6 Heatherman, which one I'm not sure, admitting
7 that they had no real understanding or
8 expertise or resources to get a product
9 registered outside of the U.S., but -- plus,
10 just my own understanding of where the company
11 was and where it wanted to go, I'm not sure
12 whether they had been -- done their IPO then
13 or not, but I mean my sense was they were
14 focusing on getting Niaspan onto the market,
15 getting it to be a success in the market, and
16 then they would deal with other opportunities
17 later down the road."

18 MR. RAOFIELD: Page 57, line 12:

19 "QUESTION: When you're working on a
20 project, what would you do if you got that
21 data? Would you analyze it yourself?

22 "ANSWER: It depends upon the product.

23 "QUESTION: Could you explain?

24 "ANSWER: If it's an area that I felt very
25 comfortable -- that I felt I had an expertise

1 in that particular area, if there was -- if I
2 looked at the data, there was -- there was
3 nothing there that was alarming, I may not get
4 an outside consultant, outside consulting
5 being going to somebody perhaps in other
6 research division or what have you.

7 "Conversely, if it's a -- certainly if it's
8 a new chemical entity, for example, or a
9 unique type of product in terms of some very
10 different type of delivery system or what have
11 you, then in that case I would probably seek
12 some additional input from one of our
13 scientists or potentially outside
14 investigators."

15 MR. RAOFIELD: Page 77, line 7:

16 "QUESTION: At some point in time, did you
17 stop working on the Kos Niaspan product?

18 "ANSWER: Yeah.

19 "QUESTION: Do you recall why?

20 "ANSWER: Well, based on certainly my first
21 conversation with Kos, it appeared to me that
22 they were going to be very, very difficult to
23 work with, and more importantly, what they
24 were looking for in terms of a deal is
25 something -- I took the position that I

1 thought it was highly unlikely that we would
2 be able to come to a deal that both sides
3 would agree to, and the way I always
4 envisioned the international, if there were a
5 deal, there would only be an international
6 deal if they -- if there was first a U.S.
7 deal, and based on, you know, certainly my --
8 you know, the one particular conference call
9 we talked about, I had very strong
10 reservations whether there was actually going
11 to be a deal at all.

12 "QUESTION: Are you saying you don't do
13 international deals unless you do -- first do
14 a U.S. deal?

15 "ANSWER: No, we do -- we do some, but
16 usually you do a U.S. deal -- you do that
17 first usually.

18 "QUESTION: Did you do a U.S. deal first on
19 Niacor?

20 "ANSWER: No, not that I -- as I say, it
21 doesn't -- we market -- some of the products,
22 we only do the international deal.

23 "QUESTION: Did you consider doing an
24 international deal on Niaspan whether or not
25 they had a U.S. deal?

1 "ANSWER: I -- no, because I -- I
2 personally didn't want to work with those
3 people, quite frankly. They -- they were -- I
4 knew those people. I saw how unreasonable
5 they were in dealing with their U.S. position.
6 I really would have preferred not to deal with
7 them.

8 "QUESTION: You didn't like them?

9 "ANSWER: I found them extremely --
10 extremely difficult to rationalize with."

11 MR. RAOFIELD: Page 132, line 7, complaint
12 counsel questioning the witness:

13 "QUESTION: Do you remember anything you
14 learned in your examination of the Kos Niaspan
15 product that was helpful to you in doing your
16 estimates of the sales forecasts for
17 Niacor-SR?

18 "ANSWER: Yes.

19 "QUESTION: And what specifically did you
20 learn that was useful?

21 "ANSWER: Well, the most important thing I
22 learned in discussions with Kos is that it was
23 possible to develop a sustained-release niacin
24 product that was efficacious as well as had a
25 good safety profile, and based on what Kos had

1 told us, that they were in final negotiations
2 with labeling with the FDA, would tell me that
3 it was also a product that the Food and Drug
4 Administration had deemed to be safe and
5 effective.

6 "So, the bottom -- the most important thing
7 to me which came out of the Niaspan
8 discussions, that, in fact, people had been
9 able to develop sustained-release formulations
10 in niacin that are both safe and effective and
11 would be worthy of regulatory approval.

12 "QUESTION: In your experience, are all
13 sustained-release mechanisms equivalent?

14 "ANSWER: No.

15 "QUESTION: What makes you think that
16 because Kos was able to make a safe and
17 effective sustained-release niacin product,
18 Upsher-Smith would make a safe and effective
19 niacin product?

20 "ANSWER: It was -- based on my vast
21 experience in the sustained-release area,
22 it's -- it's possible, once somebody can do
23 it, it's not difficult -- it's not too
24 difficult for other people to do the same
25 thing.

1 "QUESTION: And you just assumed that
2 Upsher-Smith would have the ability to do the
3 same thing?

4 "ANSWER: Well, that was certainly
5 supported by the data here.

6 "QUESTION: Okay.

7 "ANSWER: The clinical information that
8 they provided me said this product does have
9 efficacy, does have an acceptable safety
10 profile, so again, Niaspan to me was the proof
11 of concept, that they actually had shown --
12 because as we discussed before, previous
13 sustained-release niacin products had had
14 unacceptable safety profiles. Clearly Kos had
15 now shown that one could develop a good
16 sustained-release niacin product that was safe
17 and efficacious, and then when I looked at the
18 Niacor data, I saw also that they had a good
19 efficacy profile and a good safety profile."

20 MR. RAOFIELD: Page 150, line 10:

21 "QUESTION: And you assumed the product
22 would be reimbursed in most major markets then
23 for your analysis?

24 "ANSWER: Yes.

25 "QUESTION: What was that assumption based

1 on?

2 "ANSWER: The assumption was based on that
3 cholesterol-lowering is an area in which
4 virtually all health authorities are
5 interested in doing, but at the same time,
6 they're concerned about the price, and I
7 thought it -- what I saw as a real opportunity
8 for Niacor-SR was to actually provide the
9 governments with an effective, albeit, you
10 know, less effective agent than statins, but
11 an effective agent for treatment of
12 cholesterol at a much lower price than what
13 they were currently paying in statins.

14 "For example, I know in the Italian market,
15 the Italian market, Italy, you cannot get
16 reimbursement for a statin unless you either
17 have a history of a heart attack or you have a
18 family history of cardiovascular disease.
19 And, you know, a number of governments have
20 been very open in saying that they wished they
21 could put everybody on statins, but the fact
22 is they just can't afford it financially. So,
23 I saw a real opportunity here for Niacor-SR as
24 going into the marketplace with a -- with a
25 cheaper-priced product that still provides

1 some benefit in addressing patients'
2 cholesterol needs."

3 MR. RAOFIELD: Page 152, line 20, complaint
4 counsel questioning the witness:

5 "QUESTION: Haven't you from time to time
6 in the past gone to your international
7 subsidiaries to get information to determine
8 what the local rules are in pricing products?

9 "ANSWER: Just to better understand the
10 dynamics, sure.

11 "QUESTION: Did you do that here?

12 "ANSWER: No.

13 "QUESTION: Why not?

14 "ANSWER: Because I don't think it was
15 necessary based on what I saw with the --
16 based on my knowledge of what the health
17 systems were looking for, the profile of the
18 product, I -- it was -- I came to the
19 conclusion that there was a high likelihood
20 that this product would, in fact, be approved
21 and be approved for reimbursement in most of
22 the major markets.

23 "QUESTION: If that's true, then, why did
24 you send out your earlier questionnaire in
25 March on the Niaspan product?

1 "ANSWER: I'm not sure why. I might have
2 sent it out because somebody asked me to send
3 it out. I don't know why specifically I sent
4 it out. As I mentioned before, you know, my
5 experience has been that asking the
6 subsidiaries for information in areas in which
7 they're not actively involved promoting
8 doesn't often lead to very good information."

9 MR. RAOFIELD: Page 196, line 19, complaint
10 counsel questioning the witness:

11 "QUESTION: In making your sales forecast,
12 did you assume that at some point the Kos
13 Niaspan product would be marketed outside the
14 United States, Canada and Mexico?

15 "ANSWER: Yes, yes.

16 "QUESTION: And when would that have been?

17 "ANSWER: Let me go back to that document,
18 but that's --

19 "QUESTION: Exhibit 9?

20 "ANSWER: Late 2002.

21 "QUESTION: Turning to the page numbered SP
22 1600047, which has your sales projections on
23 it, you show a slight decline in sales of
24 Niacor-SR between the year 2002 and 2003. Is
25 that right?

1 "ANSWER: Yes.

2 "QUESTION: Is that decline based on the
3 competition you'd expect to see from Kos?

4 "ANSWER: Yes, that would -- because I
5 would be dropping my market share. As you'll
6 notice, my market share in 2002 is 1.5 percent
7 and in 2003 is 1.25 percent. So, I'm
8 attributing that loss of market share due to
9 increased competition.

10 "QUESTION: From Kos?

11 "ANSWER: Well, not even Kos. I mean, that
12 was the only -- you know, right now that was
13 the only game, but basically to put together
14 what I believed was a conservative estimate, I
15 made the assumption that by the time 2002 came
16 around, there could be Kos or there could be
17 potentially other products out there,
18 sustained-release niacin products with those
19 types of claims in that type of time.

20 "QUESTION: So, your assumption was that if
21 Kos came onto the market in 2002, by 2003, you
22 would still retain five-sixths of your
23 original market share?

24 "ANSWER: Yes, because what I would
25 envision happening there is that the

1 percentage right now -- when you see 1.5
2 percent in 2002, that means Niacor-SR has 1.5
3 percent market share, and it also means
4 sustained-release niacins have 1.5 percent
5 market share. When you go to 2003, our
6 particular -- the market share for Niacor-SR
7 drops to 1.25 percent. What I would envision
8 happening is that the percentage, the market
9 share for the total sustained-release niacin
10 product, would actually grow, because I do
11 believe if you have several products out
12 there, where actually the share of the market
13 that's applied to sustained-release niacin is
14 actually growing."

15 MR. RAOFIELD: Page 231, line 5:

16 "QUESTION: Mr. Audibert, would it be fair
17 to say that you did a written financial
18 assessment of the proposed Niacor-SR licensing
19 opportunity?

20 "ANSWER: If the -- if one defines the
21 opportunity as what is the financial
22 assessment should we have the ability to
23 market Niacor-SR internationally, the answer
24 is yes."

25 MR. RAOFIELD: Your Honor, that concludes

1 Schering's counter-designations for Mr. Audibert's
2 deposition.

3 MR. CARNEY: Your Honor, Upsher-Smith has no
4 live counter-designations; however, we do plan to move
5 for the admission of its designations --
6 counter-designations to complaint counsel's broader
7 deposition excerpts that you allowed us to designate I
8 think on the 22nd or 23rd of January before the close
9 of complaint counsel's case.

10 MS. SHORES: Schering also has some
11 counter-designations to the broader set of designations
12 that complaint counsel has submitted, and as I
13 understand it, complaint counsel has no objection to
14 our admitting those now.

15 JUDGE CHAPPELL: Okay, you're talking about
16 counter-designations to the -- to the depositions
17 themselves, not the excerpts we're reading in Court?

18 MS. SHORES: That's correct, Your Honor.

19 MR. CARNEY: Yes, Your Honor.

20 JUDGE CHAPPELL: All right, we'll handle that
21 at that time. Thank you.

22 Complaint counsel, call your next witness.

23 MS. BOKAT: We have no additional witnesses,
24 Your Honor. That concludes our case in chief.

25 JUDGE CHAPPELL: Does the Government rest?

1 MS. BOKAT: Pending rebuttal after defense,
2 yes, we do.

3 JUDGE CHAPPELL: Okay, it's about 1:15.
4 Before -- Schering, I -- and Upsher, I assume you have
5 a defense to put on. Is that correct?

6 MS. SHORES: We do, Your Honor.

7 We had, for the record, understood that we
8 would be submitting our counter-designations in the
9 Government's case in chief. I'm not sure -- it may be
10 form over substance, but what we have now in the
11 Government's case in chief is just their designations
12 with no counter-designations by the respondents.

13 JUDGE CHAPPELL: Okay, you're talking about
14 designating exhibits for the record. Is that right?
15 Is that what you're talking about?

16 MS. SHORES: Yes, I'm talking about -- these
17 are marked as exhibits, but again, they're the
18 counter-designations to the broader set of deposition
19 designations. The record would look incomplete if
20 there were no counter-designations from the respondents
21 put together with those designations.

22 JUDGE CHAPPELL: You may -- you may introduce
23 those whenever you want to. Do you want to do that
24 now?

25 MS. SHORES: I would prefer to do it now, Your

1 Honor.

2 JUDGE CHAPPELL: Okay.

3 MS. SHORES: As I understand it, complaint
4 counsel has no objection, and the exhibits are marked
5 SPX 1222 to 1266.

6 JUDGE CHAPPELL: Consecutively?

7 MS. SHORES: Consecutively, yes, sir.

8 JUDGE CHAPPELL: Any objection?

9 MS. BOKAT: No, Your Honor.

10 JUDGE CHAPPELL: Is Upsher objecting?

11 MR. CURRAN: No objection.

12 MR. CARNEY: No objection.

13 JUDGE CHAPPELL: Okay, give me those numbers
14 again.

15 MS. SHORES: SPX 1222 to 1266, Your Honor.

16 JUDGE CHAPPELL: SPX 1222 through 1266?

17 MS. SHORES: 66, that's right.

18 JUDGE CHAPPELL: Are admitted.

19 (SPX Exhibit Numbers 1222 through 1266 were
20 admitted into evidence.)

21 JUDGE CHAPPELL: Anything else?

22 MS. SHORES: Nothing from Schering.

23 MR. CARNEY: Your Honor, Upsher-Smith is
24 similarly making counter-designations to the
25 Government's case in chief under the rule of

1 completeness. The exhibits are USX 1500 through 1544.

2 I pause because there was some question about a
3 couple exhibits at the end that we understood complaint
4 counsel might be entering into evidence today, and, of
5 course, we are only counter-designating to exhibits
6 that they are moving into evidence.

7 JUDGE CHAPPELL: They've just rested their
8 case, so that should be cleared up at this point, Mr.
9 Carney.

10 MR. CARNEY: Okay, in that case, let me just --
11 it's 1500 through 1542, and those are
12 counter-designations to testimony which has been --
13 deposition testimony which has been admitted into
14 evidence.

15 JUDGE CHAPPELL: 1500 through 1542, and those
16 run consecutively with no missing numbers?

17 MR. CARNEY: They are consecutive undesignated
18 numbers before today, yes.

19 JUDGE CHAPPELL: And Ms. Shores, I meant to ask
20 you that for the record. Your 1222 through 1266 are
21 consecutive and there are no missing numbers between
22 there?

23 MS. SHORES: That's correct, Your Honor.

24 JUDGE CHAPPELL: Okay. Any objection to USX
25 1500 through 1542?

1 MS. BOKAT: No, Your Honor.

2 JUDGE CHAPPELL: USX 1500 through 1542 are
3 admitted.

4 (USX Exhibit Numbers 1500 through 1542 were
5 admitted into evidence.)

6 JUDGE CHAPPELL: Mr. Curran?

7 MR. CURRAN: Yes. On a separate subject, Your
8 Honor, now that complaint counsel has rested,
9 Upsher-Smith has some motions it would like to make.
10 Would you like to entertain those at this time or after
11 a lunch break?

12 JUDGE CHAPPELL: Proceed.

13 MR. CURRAN: Your Honor, Mr. Gidley will be
14 making these motions to the Court.

15 JUDGE CHAPPELL: Okay.

16 MR. GIDLEY: Your Honor, Upsher-Smith moves for
17 dismissal at the close of complaint counsel's case in
18 chief. This procedure is expressly noted and provided
19 for in the Commission's rules in Rule 3.22(e). This is
20 a motion analogous to a motion for a directed verdict,
21 and that rule provides that at the conclusion of
22 complaint counsel's case in chief, the respondents may
23 move for the failure to prove a prima facie case.

24 Our grounds include, among other grounds, Your
25 Honor, the following, and we planned, Your Honor, to

1 offer a written memorandum to set forth the grounds
2 more formally, but I want to put them into the record
3 now so Your Honor has those grounds before him this
4 afternoon.

5 JUDGE CHAPPELL: If you're doing it in writing,
6 are you making the motion now or later?

7 MR. GIDLEY: I'm making the motion now, Your
8 Honor, but we will follow with a memorandum of law. We
9 will probably get that in on Monday, and we are not
10 asking for an adjournment of proceedings. Obviously
11 witnesses have traveled from a distance, the Court is
12 here. In the interest of judicial economy, we expect
13 the evidence to proceed, but we will be following very
14 shortly with a memorandum of law.

15 JUDGE CHAPPELL: So, you don't expect a ruling
16 until your written filing?

17 MR. GIDLEY: And a chance to have the complaint
18 counsel respond, I think that's right, Your Honor, but
19 I would like to go ahead and make the motion now for
20 the record.

21 JUDGE CHAPPELL: So, just so I understand where
22 we are here, you're going to pretty much orally argue a
23 motion that you haven't filed yet?

24 MR. GIDLEY: That's correct, Your Honor. I'm
25 going to set forth the basic grounds for motion.

1 JUDGE CHAPPELL: Okay, proceed.

2 MR. GIDLEY: Thank you, Your Honor.

3 The first, Your Honor, is with respect to Count
4 4 which alleges a conspiracy to monopolize. There have
5 been at least two failures in our view. First, there
6 has been no proof that Upsher-Smith ever formed the
7 specific intent to further a Schering-Plough monopoly
8 in potassium or any other product. The courts are very
9 precise that there may be -- there must be more than a
10 general intent, but a specific intent, and I would
11 direct the Court's attention to the case In Re:
12 Microsoft, 127 F. 2d 728, in which Judge Motz indicated
13 that a defendant must form the conscious desire, and
14 here there has been no evidence that Upsher-Smith
15 formed a conscious desire to further Schering-Plough's
16 alleged monopoly.

17 Second, Your Honor, there is no proof of a
18 conspiracy to monopolize. Mr. Bresnahan testified that
19 he could not say that any particular individual was a
20 member of any conspiracy. He had reviewed many IHs and
21 depositions but could not name a conspirator, and he
22 conceded that the executives here did not behave in a
23 furtive, secretive way.

24 The second point we would make, Your Honor, is
25 with respect to the 180 days. Paragraphs 41, 42, 47

1 and 66 address the 180-day issue in the complaint. The
2 complaint boldly states that the June agreement had the
3 effect of delaying entry into the relevant market. We
4 would observe here first, Your Honor, there's
5 absolutely no evidence of intent that can be applied at
6 the time of the June 17, 1997 agreement.

7 In fact, very late last night, as the Court is
8 painfully aware, Mr. Hoffman indicated that it was
9 substantially uncertain what the state of the law was,
10 and there is no proof that Upsher-Smith or
11 Schering-Plough for that matter formed any intent or
12 was conscious of the exclusivity provision in entering
13 into the June agreement.

14 But more fundamentally, Your Honor, there is no
15 evidence that any firm has been blocked. The complaint
16 mentions the Andrx firm in paragraphs 61 and 62, but
17 the Andrx drug could not have been approved. Mr.
18 Rosenthal testified in the case in chief that that firm
19 has not been blocked. Further, Professor Bresnahan
20 could name no firm that has been blocked by the 180-day
21 period which will expire at the end of this month.

22 Finally, Your Honor, very last late night, Mr.
23 Hoffman went through other scenarios, other settlements
24 and with commercial marketing would have triggered 180
25 days, and had there been litigation, either my client

1 would have been blocked from the market until 2006, or
2 if we had won a lawsuit, there would have been 180
3 days. So, this issue truly is a red herring. There is
4 no proof of a manipulation of the 180 days, which was a
5 ground for Your Honor denying the motion to dismiss
6 back in October.

7 Third, Your Honor, Count 1 must be dismissed.
8 Count 1 alleges an anti-competitive agreement with
9 anti-competitive effect. Basically Count 1 appears to
10 incorporate the Bresnahan rule. We would observe
11 first, Your Honor, that there's been a failure, a
12 fundamental failure, to establish a product market.
13 There was tepid advancement by complaint counsel of an
14 alleged 20 mEq product market, but the legal standard
15 for that product market is set forth in the Supreme
16 Court's decision in Brown Shoe, which sets forth seven
17 factors.

18 Professor Bresnahan, in his witness
19 testimony -- in his testimony, testified that the
20 majority of those factors support a much broader market
21 in terms of industry recognition. In terms of the
22 documents in the case in chief, they all suggest a
23 potassium market. It was Mr. Teagarden I believe who
24 testified 24 different potassium products were
25 therapeutically equivalent. There was abundant

1 testimony that two of the 10 mEq tablets would be
2 interchangeable in use and purpose for the 20 mEq
3 tablets.

4 By no means am I giving a full summary of the
5 evidence, but the evidence was ample that there was a
6 broader market.

7 Moreover, there was no proof of a monopoly by
8 Schering in that broader market. Indeed, there was
9 ample proof that Upsher-Smith, Schering and many other
10 firms were competing in a crowded market.

11 With respect to the Bresnahan rule, which
12 frankly, Your Honor, I'm not sure where to pigeonhole
13 it legally, but taking it as complaint counsel's main
14 theory for why the agreement is anti-competitive, the
15 Bresnahan rule has not been satisfied in either prongs
16 one or three, and frankly, not even prong two.

17 Prong one alleges a monopoly in a relevant
18 product market; that has not been demonstrated legally.
19 Prong three talks about a payment for delay, but
20 complaint counsel, which have consistently acknowledged
21 that it must prove that Schering paid for delay, has
22 not adduced evidence that the executives believed they
23 were paying for delay. There has not been that factual
24 testimony in either the IHs or in the deposition
25 transcripts that have been read in this courtroom.

1 Finally, Your Honor, we believe that the
2 agreement, the June 17, 1997 agreement, must be
3 considered under the rule of reason. This is a novel
4 restraint. The Court has read hundreds of pages of
5 motion to dismiss briefs, and the Court I am sure --

6 JUDGE CHAPPELL: I'm willing to bet it's
7 thousands, Mr. Gidley.

8 MR. GIDLEY: Thousands of pages, and you've no
9 doubt opened the law books to a number of cases that
10 may be analogous, but this is a case of first
11 impression, and the courts are very leery of imposing
12 per se characterizations when the sample class of
13 restraints is one, which is exactly the instance here.

14 Under the rule of reason, complaint counsel
15 must prove an intent to harm competition, which has not
16 been established, and that's a general intent, and
17 second, there must be a weighing of pro and
18 anti-competitive effects of the restraint. Professor
19 Bresnahan explicitly did not do that weighing.

20 Finally, Your Honor, there is this issue of the
21 other tablet or design-around. That's that extra
22 language that occurs right in that September 1 passage
23 in the June 17, 1997 agreement, and for reference
24 purposes, Your Honor, the complaint references this
25 argument in paragraph 44. This is the other tablet

1 restriction.

2 Professor Bresnahan testified at length that
3 he's reviewed all the documents and the IHs and the
4 depositions, but he's uncovered no other product other
5 than the Klor Con M20 product, which was actually
6 blocked by that language, and I asked him on this
7 witness stand, was there any chemist or any patent or
8 any other theory of a theoretical additional product.
9 There is no such product.

10 Finally, Your Honor, without belaboring the
11 point, we have made the point previously in our trial
12 brief that under the cases of Ethyl, General Electric
13 and even Masonite, which complaint counsel rely upon,
14 the relevant law here is that a patent is a lawful
15 monopoly within the four corners of the patent.
16 Agreements by patent holders to extend the monopoly
17 into other products have received careful judicial
18 scrutiny.

19 Here, Your Honor, the only restraint shortens
20 within the four corners of the patent the scope of the
21 patent. Such a license agreement where, as here, there
22 is no evidence in the case in chief of the patent being
23 invalid or that it was not infringed by my client we
24 would say compels a ruling in our favor.

25 We will, Your Honor, provide a written

1 memorandum of law for the convenience of the Court and
2 for complaint counsel, but we would so move the Court
3 on those grounds.

4 JUDGE CHAPPELL: Is this a joint motion by both
5 respondents?

6 MR. GIDLEY: I am moving on behalf of
7 respondent Upsher-Smith.

8 JUDGE CHAPPELL: And as I understand it, you're
9 going to file a written motion and memorandum?

10 MR. GIDLEY: Yes, on Monday morning.

11 JUDGE CHAPPELL: Mr. Nields?

12 MR. NIELDS: Yes, I don't think that was a
13 joint motion, Your Honor. We would also move to
14 dismiss at the close of the Government's case on the
15 ground that complaint counsel has failed to prove that
16 either of these settlement agreements was, in fact,
17 unreasonable.

18 JUDGE CHAPPELL: Let me stop you just a second.

19 Does complaint counsel wish to respond to
20 Upsher's motion before Mr. Nields makes his motion?

21 MS. BOKAT: I'm willing to let Mr. Nields
22 proceed and then respond to both of them.

23 JUDGE CHAPPELL: Okay.

24 You may proceed.

25 MR. NIELDS: I had actually --

1 JUDGE CHAPPELL: Do you need her to read back
2 your last statement?

3 MR. NIELDS: I don't need to. I had actually
4 finished, Your Honor. I believe they have not
5 sustained their burden of proof that either agreement
6 was, in fact, an unreasonable restraint of trade.

7 JUDGE CHAPPELL: Okay. Will Schering-Plough
8 also be filing a written motion and memorandum?

9 MR. NIELDS: We had not planned to file a
10 memorandum, Your Honor. We had not planned to burden
11 the Court. If the Court would like to have a document
12 rather than just an oral motion, we would certainly be
13 willing to do that, and we could file it Monday as
14 well.

15 JUDGE CHAPPELL: Let me hear the Government's
16 response and then I'll let you know what I need on
17 that.

18 MR. NIELDS: Thank you, Your Honor.

19 JUDGE CHAPPELL: Ms. Bokat?

20 MS. BOKAT: Thank you, Your Honor.

21 We, of course, will be filing a written answer
22 after we see the written motions and memoranda. Just a
23 couple of brief points orally.

24 We feel we have provided ample proof that both
25 the agreements, Schering's agreement with Upsher-Smith

1 and Schering's agreement with ESI Lederle, are
2 anti-competitive. They delayed entry into the market
3 and harmed consumers thereby because they delayed the
4 entry of lower-priced generic competition, and
5 consumers were forced to continue paying the higher
6 branded price for K-Dur 20.

7 Mr. Gidley, in talking about Count 1 on the
8 horizontal agreements is contending that we had not
9 proved a product market. What he failed to mention is
10 that in horizontal agreement cases, proof of a product
11 market is merely a proxy for competitive effects. If
12 the plaintiff can't show actual effects, they can infer
13 effects by proving a product market.

14 Here, we believe we showed actual effects on
15 the price until September 2001. So, it's not necessary
16 to define a product market. We've already proved the
17 effect, which is sufficient for the horizontal
18 agreement.

19 On the conspiracy -- I'm sorry, the
20 monopolization and the conspiracy to monopolize counts,
21 the agreements themselves demonstrate the intent to
22 preserve Schering's monopoly in the 20 milliequivalent
23 potassium chloride tablet and capsule market. Those
24 documents alone establish the intent and the
25 conspiracy.

1 Of course, there's additional evidence that we
2 will probably point to in our written answer. I merely
3 wanted to make those brief points orally this
4 afternoon.

5 JUDGE CHAPPELL: Do you want to respond to his
6 rule of reason issue?

7 MS. BOKAT: Certainly.

8 We could prove this case through three
9 different analytical frameworks, per se, a quick look
10 rule of reason and a full rule of reason. Any one of
11 those would be sufficient to find a violation of the
12 antitrust laws. We believe we have satisfied all three
13 counts.

14 The Court could find these agreements to be per
15 se illegal because on their face they restrained
16 output. We believe, as I discussed earlier, that we've
17 also proved the case under the rule of reason, because
18 we have shown actual competitive effects. So,
19 whichever analytical framework the Court ultimately
20 chooses, we believe we have satisfied the burden.

21 JUDGE CHAPPELL: Okay, thank you.

22 MS. BOKAT: Thank you.

23 JUDGE CHAPPELL: Okay, based on Mr. Gidley's
24 request, I will take the oral motion under advisement
25 until I get the written motion and memoranda in support

1 thereof, and as soon as I have the response, I will
2 rule promptly.

3 MR. NIELDS: Thank you, Your Honor. May I be
4 permitted to just add a word, because it occurs to me
5 that it is worth mentioning.

6 JUDGE CHAPPELL: You mean a few words?

7 MR. NIELDS: A few words.

8 JUDGE CHAPPELL: Yes.

9 MR. NIELDS: Thank you, Your Honor.

10 We have heard virtually nothing about the ESI
11 agreement here, and we believe that there is a complete
12 failure of proof that the ESI agreement was an
13 unreasonable restraint of trade. It is an agreement
14 which based on what is in the record was concededly
15 worked out by and approved by Judge Reuter, a United
16 States Magistrate Judge in Federal Court in
17 Philadelphia, and I believe, Your Honor, that complaint
18 counsel has to do a lot more than what they've done now
19 in order to support a finding that that agreement is an
20 unreasonable restraint of trade in violation of the
21 antitrust laws.

22 JUDGE CHAPPELL: Okay. I gave him a few words,
23 so I'll give complaint counsel a few words if you'd
24 like.

25 MS. BOKAT: Thank you, Your Honor.

1 Our evidence includes the agreement between
2 Schering and ESI. You've heard the explanation from
3 Professor Bresnahan about that agreement. The
4 designations from the transcripts of Michael Dey and
5 Lawrence Alaburda, both officials with ESI, provide
6 additional evidence. If we look just at the settlement
7 agreement --

8 JUDGE CHAPPELL: So, you are saying there is a
9 lot of evidence other than what we've heard in open
10 court?

11 MS. BOKAT: That's right.

12 If we focus just on the settlement agreement
13 between Schering and ESI, leaving aside for a moment
14 the licensing agreement, the settlement agreement
15 provided that Schering would pay ESI at least \$5
16 million and up to \$15 million. The amount was going to
17 depend on how quickly ESI's product got tentative
18 approval from the FDA and became a real competitive
19 threat. So, there was payment.

20 In return, ESI agreed that they will not bring
21 their generic to market until January 2004 at the
22 earliest. It's a clear payment for delay. There was
23 not even a license in that agreement. That was a clear
24 anti-competitive agreement. Schering was paying ESI to
25 stay off the market with their lower-cost generic until

1 January 2004, and this agreement was reached in January
2 of 1998.

3 JUDGE CHAPPELL: Okay.

4 MS. BOKAT: That's it.

5 JUDGE CHAPPELL: Thank you.

6 Any other motions?

7 MR. CURRAN: Yes, another motion, Your Honor.

8 Your Honor will recall that at the outset of
9 the case, you admitted certain transcripts and
10 documents conditionally on the condition that complaint
11 counsel prove up the alleged conspiracy in its case in
12 chief.

13 JUDGE CHAPPELL: This is one I'm definitely
14 going to want in writing, Mr. Curran.

15 MR. CURRAN: Okay, you would like that in
16 writing as well?

17 JUDGE CHAPPELL: Yes, I think that would enable
18 a better look at what you're prepared to offer to the
19 Court. I think to be fair to everybody, I would like
20 to see -- and I know where you're going, you're going
21 on the conspiracy issue, right?

22 MR. CURRAN: Right.

23 JUDGE CHAPPELL: I request that motion and any
24 response thereto to be in writing.

25 MR. CURRAN: Thank you very much, Your Honor.

1 JUDGE CHAPPELL: Would you like to argue it
2 preemptively, or do you just want to do it in writing?

3 MR. CURRAN: I would like to do it in writing,
4 and then if Your Honor wants to entertain oral argument
5 in support of the motion, we can do that at your
6 pleasure.

7 JUDGE CHAPPELL: Okay, thank you.
8 Anything else?

9 MR. CURRAN: Nothing for Upsher-Smith, Your
10 Honor.

11 JUDGE CHAPPELL: Who's going to present their
12 defense first, Schering-Plough or Upsher?

13 MR. NIELDS: Schering, Your Honor, and as I
14 think the Court may recall, we are going to begin with
15 proof regarding the ESI agreement, then we'll move to
16 proof regarding the Upsher-Smith agreement, and that
17 will lead to the Upsher-Smith case.

18 JUDGE CHAPPELL: Okay, and I've got a pending
19 motion that I'm going to rule on very shortly regarding
20 excluding some evidence. Will those issues be touched
21 upon immediately?

22 MR. NIELDS: Yes, they will, Your Honor.

23 JUDGE CHAPPELL: Mr. Curran, we are going to
24 have your response -- what is this -- tomorrow, Friday?

25 MR. CURRAN: I guess I offered that. I

1 certainly hope that doesn't mean that proceedings are
2 held up until then.

3 JUDGE CHAPPELL: No, it -- but it occurs to me
4 after reviewing the motions, to use a word I saw
5 yesterday on the ELMO, both parties are entangled in
6 the issue, and I will make a ruling this afternoon as
7 to Schering-Plough and reserve my ruling as to
8 Upsher until I read your response, but you're going to
9 know where I'm going very early, just so you'll know,
10 but I will consider your response when it's filed
11 tomorrow.

12 I think it's about 1:40. I'm going to take
13 about a 45-minute break. If you haven't had lunch,
14 this will be your last opportunity. And if I can add
15 the numbers right, why don't we reconvene at -- why
16 don't we just say 2:30. We will reconvene at 2:30.
17 Thank you.

18 (A brief recess was taken.)

19 JUDGE CHAPPELL: Mr. Nields, are you ready to
20 call your first witness?

21 MR. NIELDS: I am, Your Honor.

22 JUDGE CHAPPELL: Okay, hold on a second.

23 I have pending complaint counsel's motion and
24 memo in support of motion to preclude certain testimony
25 of respondents' lawyer witnesses, and I have the

1 response in opposition filed by Schering-Plough.

2 According to the Government, certain
3 information was requested during the discovery, whether
4 it was production requests or depositions, et cetera,
5 and privilege was claimed by the respondents.

6 According to the respondents -- and I'm just
7 highlighting a few things -- oh, I left out also, the
8 Government is now aware of this due to representations
9 made in the opening statements of both respondents.

10 And I would point out to the Government, they
11 refer in their motion to opening argument. They are,
12 in fact, opening statements, not opening arguments. We
13 have closing arguments, but just a technicality there.

14 One of my jobs is to somehow manage
15 introduction of evidence and testimony in the case, and
16 my ruling is my conclusion of the only way that this
17 can be managed, and my ruling is as follows:

18 The respondents are not allowed to introduce
19 any testimony or evidence of anything that was asked
20 for by the Government and that was not given up, that
21 was retained because of privilege or any other
22 objection, and I mean directly, indirectly or
23 otherwise, it's not coming in, and that's to be fair.

24 Discovery is a two-way street. If someone asks
25 for something and you don't give it, you don't use it.

1 It's just that simple. I will not allow anything to
2 come in that was withheld on the ground of privilege.

3 The parties are going to have to police this
4 ruling. If there's a question asked and it was asked
5 at a deposition, I want to hear an objection if there
6 was a privilege objection made or any other objection.

7 Any questions on my ruling?

8 I should say that you now know the motion was
9 granted in part and denied in part, and I will -- and
10 my ruling as of now goes to Schering-Plough only. I
11 will rule as to Upsher-Smith, to the extent I need to,
12 after I see their response on Friday.

13 Mr. Nields, any questions?

14 MR. NIELDS: I don't think so, Your Honor. I
15 think that's clear as a bell, and we will abide by it.

16 JUDGE CHAPPELL: Government? Someone stand --

17 MS. BOKAT: No, Your Honor.

18 MR. EISENSTAT: No, Your Honor.

19 JUDGE CHAPPELL: Don't hang yourself with that
20 ID here.

21 JUDGE CHAPPELL: Mr. Curran?

22 MR. CURRAN: Your Honor, I have no questions
23 either. I'm prepared to abide by that order, and if
24 that would obviate our filing an opposition, I could
25 live with that as well, Your Honor.

1 JUDGE CHAPPELL: I take it you would join in
2 the opposition that was previously filed by
3 Schering-Plough?

4 MR. CURRAN: That might make things easiest,
5 and I would. I have read that.

6 JUDGE CHAPPELL: And perhaps that will save you
7 some work since I think it's clear what my ruling will
8 be as to Upsher.

9 MR. CURRAN: I've got a good inkling on that
10 subject.

11 JUDGE CHAPPELL: I appreciate that offer, Mr.
12 Curran. So, therefore, the motion is granted in part
13 and denied in part as to both parties, both
14 respondents.

15 With that, we will proceed. Call your first
16 witness, Mr. Nields.

17 MR. NIELDS: Your Honor, Schering calls Anthony
18 Herman, and I have some books of exhibits to hand out
19 if I may do that.

20 JUDGE CHAPPELL: Also, I wanted to know if
21 pursuant to the ruling I just made, do you need some
22 time to look over your notes regarding your examination
23 of the witness?

24 MR. NIELDS: Your Honor, not knowing what the
25 Court was going to say, it occurred to me that that

1 might be necessary, but as I understand the Court's
2 ruling, it is if we withheld something or objected on
3 grounds of privilege, we can't use it, period. We are
4 completely comfortable with that and would not have
5 done it anyway. So, I don't think we need to do any
6 consultation.

7 JUDGE CHAPPELL: Okay, let's proceed.

8 Raise your right hand.

9 Whereupon--

10 ANTHONY HERMAN

11 a witness, called for examination, having been first
12 duly sworn, was examined and testified as follows:

13 JUDGE CHAPPELL: Have a seat.

14 Does the witness have water?

15 MR. NIELDS: I'm sorry, Your Honor?

16 JUDGE CHAPPELL: I want to make sure the
17 witness has some water. I see a thermos, but I don't
18 know if there are any cups or water there.

19 THE WITNESS: Thank you, Your Honor.

20 JUDGE CHAPPELL: And I need you to state your
21 full name for the record, sir.

22 THE WITNESS: Anthony Herman.

23 JUDGE CHAPPELL: Thank you.

24 Whenever you're ready, you may proceed, Mr.
25 Nields.

1 MR. NIELDS: Thank you, Your Honor.

2 DIRECT EXAMINATION

3 BY MR. NIELDS:

4 Q. Good afternoon, Mr. Herman.

5 A. Mr. Nields.

6 Q. Would you state your name?

7 A. Anthony Herman.

8 Q. And how are you employed, Mr. Herman?

9 A. I'm a partner in the law firm of Covington &
10 Burling.

11 Q. Would you state your educational background?

12 A. Yes. I have a BA from the University of South
13 Carolina, and I graduated magna cum laude from Harvard
14 Law School in 1986.

15 Q. What has your job history, job experience been
16 since 1986 when you graduated from law school?

17 A. Immediately after graduating from law school, I
18 was a summer associate at Ropes & Gray in Boston. I
19 then was a law clerk for Judge Irving L. Goldberg in
20 the United States Court of Appeals for the Fifth
21 Circuit. For the year 1987, I was a law professor at
22 the Florida State University College of Law, where I
23 worked until 1989. I then became an associate at
24 Covington & Burling in Washington and became a partner
25 in 1994.

1 Q. Do you specialize in any particular kind of
2 law?

3 A. I do, Mr. Nields. I am a litigator with a
4 particular focus on intellectual property and patent
5 litigation.

6 Q. This case is about the settlement of a lawsuit
7 by Key Pharmaceuticals against ESI Lederle. Did you
8 have a connection with that lawsuit?

9 A. I did. For most of the litigation, I was Key
10 Pharmaceuticals' lead counsel.

11 Q. What kind of a case was it?

12 A. A patent infringement case.

13 Q. I'd ask you to look at the exhibit that is
14 behind tab 1 in your notebook. It is marked, excuse
15 me, SPX 680. Can you identify it?

16 A. Yes, it's the complaint in the case.

17 Q. And when was it filed?

18 A. I believe it was filed in April of 1996 --
19 excuse me, I apologize, I was looking at the wrong
20 paper, Mr. Nields.

21 Q. Take your time, Mr. Herman. Don't rush.

22 A. February of 1996.

23 Q. Did there come a time when the parties
24 discussed a possible settlement of that case?

25 A. Yes.

1 Q. And when approximately did the parties first
2 start discussing a possible settlement?

3 A. I believe the parties began talking about that
4 settlement in October.

5 Q. Of 1996?

6 A. 1996, yes.

7 Q. And how did this come about?

8 A. At the urging of the presiding judge in the
9 case, Judge DuBois.

10 Q. What form did the settlement conversations
11 take?

12 A. We had a status conference with Judge DuBois,
13 and he told us that he wanted us to participate in a
14 mediation session before a United States Magistrate
15 Judge.

16 MR. EISENSTAT: I would object, Your Honor, and
17 ask you to strike the portion as to what the judge said
18 as hearsay.

19 MR. NIELDS: Your Honor, it's not being offered
20 for the truth. It's being offered for why they ended
21 up in the mediation process.

22 JUDGE CHAPPELL: I'll overrule the objection
23 and allow it to stand as to why they took certain
24 action.

25 MR. NIELDS: I'm sorry, Your Honor, I've

1 forgotten where that ended with the objection. May I
2 have a moment?

3 JUDGE CHAPPELL: You may.

4 (Counsel conferring.)

5 BY MR. NIELDS:

6 Q. Who was the United States Magistrate Judge?

7 A. Judge Reuter.

8 Q. And how long did the mediation process with
9 Judge Reuter last, approximately?

10 A. Approximately 15 months.

11 Q. Did the case eventually settle?

12 A. It did.

13 Q. And when?

14 A. I believe it was in January of 1998.

15 Q. And where?

16 A. In Judge Reuter's chambers in the courthouse in
17 Philadelphia.

18 Q. Now, I'd like you to look at a document that is
19 behind tab 34. It's a two-page handwritten document.
20 Can you identify it?

21 A. Yes, this is a document that was prepared late
22 at night on January 23rd, 198 -- 1996 that is the
23 principles of agreement that were arrived at in the --
24 in Judge Reuter's chambers.

25 Q. And whose writing is it?

1 A. It's the writing of Paul Heller, who was the
2 lead lawyer for ESI Lederle.

3 Q. And who signed it?

4 A. Mr. Heller signed it and Susan Lee signed it,
5 who was the director of patent litigation for
6 Schering-Plough.

7 Q. Was Judge Reuter present at the time it was
8 prepared and signed?

9 A. He was. He, in fact, was looking over Mr.
10 Heller's shoulder as he was preparing it in the
11 secretarial area of chambers.

12 Q. The -- this document shows certain payments
13 agreed to -- agreed to be made by Key Pharmaceuticals
14 to ESI. Was Judge Reuter aware of those?

15 A. He was keenly aware of them and, in fact,
16 proposed several of the terms.

17 Q. Now, I'm going to show you a document behind
18 tab 35. It's a letter dated January 26, 1998, and it
19 bears exhibit number CX 491. Can you identify that?

20 A. Yes, this is a letter that Judge DuBois sent to
21 counsel congratulating us upon settling the case.

22 Q. The first paragraph reads, "Congratulations on
23 getting this case settled. As you know, the settlement
24 resulted in a resolution of the dispute that
25 accommodated the interests of the parties but could not

1 have been awarded by the Court at trial. It represents
2 a job well done."

3 Do you know whether Judge DuBois was aware of
4 the terms of the agreement?

5 A. I don't know directly, but I do know that Judge
6 Reuter told us that he was going to apprise Judge
7 DuBois of the terms of the settlement as he had
8 apprised Judge DuBois in detail in the course of
9 settlement negotiations during the 15-month proceeding.

10 MR. EISENSTAT: Objection again, Your Honor,
11 move to strike with respect to what Judge Reuter told
12 them as hearsay.

13 MR. NIELDS: Your Honor, I would submit that
14 this under the rules of evidence here is reliable and
15 relevant, and the Court may give it such weight as the
16 Court decides to give it, but it is of sufficient
17 reliability to be admitted.

18 MR. EISENSTAT: If I may, Your Honor, it sounds
19 like they're asking this to be admitted for the truth
20 of the matter stated, and we have just one witness'
21 word as to what went on at this conversation, and I see
22 no indicia of reliability of the kind this Court has
23 normally relied upon in its hearsay rulings.

24 MR. NIELDS: It's being offered both for the
25 truth and also simply for the fact that it was said to

1 the parties.

2 JUDGE CHAPPELL: Give me a second to look at
3 the answer.

4 I think we're getting a little far afield. We
5 have the witness saying that he knows Judge Reuter is
6 going to apprise another judge. So, I'm going to
7 sustain the objection as to the truth of the matter.

8 MR. NIELDS: Very well, Your Honor.

9 JUDGE CHAPPELL: Proceed.

10 BY MR. NIELDS:

11 Q. I should have said earlier, Mr. Herman, that
12 the two-page handwritten document behind tab 34 that I
13 think you said were the terms of the agreement in
14 principle?

15 A. Yes.

16 Q. That bears exhibit number CX 472.

17 A. Yes.

18 Q. And if you turn to the back of that exhibit,
19 it's a multipage exhibit, the last page is a
20 typewritten one-page document bearing Bates stamp SP
21 1300635. Do you see that?

22 A. Mr. Nields, that doesn't seem to be in my book.

23 MR. EISENSTAT: It's not in my book either,
24 Counsel.

25 MR. NIELDS: Your Honor, I apologize. There

1 seems to have been a slip-up.

2 JUDGE CHAPPELL: It's in my copy.

3 MR. NIELDS: Is it?

4 JUDGE CHAPPELL: 472, yes.

5 MR. NIELDS: Well, no, it's a question of
6 whether at the back of 472 -- if 472 is a two-page only
7 in yours, Your Honor, then there's something missing.

8 JUDGE CHAPPELL: Right, I have the two pages.

9 MR. NIELDS: I hope this doesn't recur. How do
10 I turn this thing on? Thank you.

11 Your Honor, it is my belief that the actual
12 Exhibit 472 is not a two-page document, but rather, a
13 five-page document as it was agreed to be admitted by
14 the parties, and I am -- I would like permission to
15 replace the two-page with the five-page at the end of
16 these proceedings today --

17 JUDGE CHAPPELL: If you want to replace it,
18 I -- this binder is just for me to follow along.
19 It's --

20 MR. NIELDS: Fine, well then we'll just use the
21 one that I have, and --

22 JUDGE CHAPPELL: Just so we're clear, you're
23 talking about the complete exhibit, and just so the
24 witness can follow you, because I don't think he can
25 read what's on the ELMO.

1 THE WITNESS: I can't read what's on the ELMO,
2 Mr. Nields.

3 MR. NIELDS: May I approach, Your Honor?

4 JUDGE CHAPPELL: Yes, you may.

5 MR. NIELDS: Your Honor, I think Ms. Shores has
6 advised me that I may be incorrect when I said that the
7 actual original exhibit has five pages. It may only
8 have two. That may be why these books were changed.

9 JUDGE CHAPPELL: That's a -- that's a complaint
10 counsel exhibit, isn't it?

11 MR. NIELDS: Yes.

12 JUDGE CHAPPELL: Can you verify how many pages
13 it should have, please?

14 MS. BOKAT: Your Honor, I pulled our binder.
15 Ours has only two pages. I'm now checking our exhibit
16 list under the Bates numbers, and it appears that
17 that's also a two-page exhibit.

18 JUDGE CHAPPELL: Okay, thank you.

19 MR. NIELDS: Your Honor, I think what that
20 means is that this --

21 JUDGE CHAPPELL: So, then, it's not the fault
22 of whoever made your copies, Mr. Nields. Let's relieve
23 them of the responsibility.

24 MR. NIELDS: Yes, Your Honor, the fault seems
25 to be mine, but the remedy I hope is to affix a new

1 exhibit number to the typewritten document.

2 JUDGE CHAPPELL: Do you have a copy for
3 complaint counsel to see?

4 MR. NIELDS: I don't, Your Honor. I just
5 have -- I just have this one.

6 JUDGE CHAPPELL: With the millions of pages in
7 this courtroom, and there is only one of that one, Mr.
8 Nields?

9 MR. NIELDS: Only one of that one.

10 JUDGE CHAPPELL: Okay. Do you need a moment?

11 MR. NIELDS: I think maybe I need a moment,
12 Your Honor. I seem to.

13 JUDGE CHAPPELL: Okay.

14 (Pause in the proceedings.)

15 MR. NIELDS: Ah, I've made some progress, Your
16 Honor.

17 JUDGE CHAPPELL: Okay.

18 MR. NIELDS: This is CX 474, page 4.

19 JUDGE CHAPPELL: Is that in the binder?

20 MR. NIELDS: It's not in the binder I don't
21 believe, Your Honor, unless it's been -- but it is a
22 complaint counsel exhibit.

23 JUDGE CHAPPELL: As soon as they verify they
24 have it and it's four pages, then you'll need to give
25 one to the witness.

1 MR. NIELDS: Okay. So, I am going to approach
2 the witness, Your Honor, with the fourth page of
3 CX 474.

4 JUDGE CHAPPELL: Yes, you may.

5 THE WITNESS: Thank you.

6 BY MR. NIELDS:

7 Q. Mr. Herman, can you identify the fourth page of
8 CX 474?

9 A. Yes. This is a typed-up version of the
10 agreements in principle that was handwritten by Mr.
11 Heller on the night of January 23rd.

12 Q. And is it an accurate but more legible
13 transcription of the typewritten document?

14 A. It is word for word identical to the
15 handwritten document.

16 Q. Thank you.

17 May I approach again, Your Honor?

18 JUDGE CHAPPELL: Yes.

19 BY MR. NIELDS:

20 Q. Mr. Herman, I would like to go back and cover
21 the mediation process in somewhat greater detail.

22 Would you turn please to the document behind
23 tab 2. It bears SPX 73, and it is dated October 16,
24 1996. Can you identify it?

25 A. Yes. This is a letter that I sent to Judge

1 DuBois reporting to him that both Key and ESI Lederle
2 had agreed to participate in mediation with Judge
3 Reuter.

4 Q. And would you turn to the document behind tab
5 3. It is a letter dated October 21, 1996 bearing SPX
6 550. Can you identify it?

7 A. This is a letter that Judge DuBois sent to
8 Judge Reuter thanking him for agreeing to preside over
9 the mediation process and telling him that in his view
10 it would be appropriate for Judge Reuter to request
11 mediation conference memoranda from the parties.

12 Q. And did the parties provide Judge Reuter with
13 mediation conference memoranda?

14 A. We did, Mr. Nields.

15 Q. Would you turn to the document behind tab 4.
16 It is a document dated November 12th, 1996, bearing SPX
17 74. Can you identify it?

18 A. Yes, this is our mediation conference
19 memorandum that was submitted to Judge Reuter through
20 our local counsel, Chuck Blakinger.

21 Q. Would you turn to the document behind tab 5.
22 It is a letter dated also November 12th, 1996 bearing
23 SPX 1204. Can you identify it?

24 A. Yes, this is a cover letter from Mr. Heller
25 enclosing a copy of ESI Lederle's mediation conference

1 memorandum.

2 Q. Now, if you turn back to the ESI memorandum,
3 which is behind tab 4, the cover letter states that
4 there's a settlement conference scheduled for November
5 19, 1996 in this case. Did such a conference take
6 place?

7 A. Yes.

8 Q. Where was it?

9 A. That mediation conference, like all the
10 mediation conferences, took place in Judge Reuter's
11 chambers in the large sense. Part of it took place in
12 Judge Reuter's courtroom and part of it took place in
13 his actual chambers, which are attached to his
14 courtroom.

15 Q. Who was there for this mediation conference
16 that you can recall?

17 A. Susan Lee, the Schering-Plough director of
18 patent litigation, was there; Mr. Heller was there; I
19 believe a colleague of his by the name of Deborah
20 Somerville was there; and the American Home Products
21 in-house patent lawyer, Larry Alaburda, I believe was
22 there.

23 Q. Now, if you turn back to tab -- the document
24 behind tab 3, that's the letter from Judge DuBois dated
25 October 21, 1996, it states at the end of paragraph 2,

1 "In addition, representatives of the parties duly
2 authorized to bind the parties should be required to
3 attend the mediation conferences."

4 Were there any business people from Schering,
5 if you recall, at the first mediation session?

6 A. I don't have a firm memory of that, Mr. Nields,
7 but it is quite possible that Marty Driscoll, who was
8 the head of Key Pharmaceuticals, was there, and perhaps
9 Michael Dey, who was the CEO of ESI Lederle, was
10 present as well.

11 Q. What occurred at that first mediation
12 conference?

13 A. At the outset, Judge Reuter had us in the
14 courtroom, and he handed out a sheet of questions and
15 presided over an oral argument. The questions provided
16 a framework for the oral argument that Mr. Heller and I
17 had on the substantive merits of the case.

18 Q. And if you would turn to the document behind
19 tab 6, it bears SPX 77. Its cover sheet has a date of
20 November 22nd, 1996, but if you go back to the third
21 page, you will see a -- what is it -- essentially a
22 two-page document, and my question is, can you identify
23 that?

24 A. Yes, this is a -- the questions sheet, the
25 discussion points for settlement that I alluded to that

1 Judge Reuter handed out during the oral argument on
2 November the 19th, along with a cover memorandum from
3 me.

4 Q. How long did this oral argument in his
5 courtroom last?

6 A. Approximately -- something between one and two
7 hours. I'm not precisely sure, Mr. Nields.

8 Q. And what followed the argument in Judge
9 Reuter's courtroom?

10 A. After the argument, Judge Reuter, as was his
11 habit, called the parties individually into his
12 chambers to explore their settlement positions.

13 Q. When you say "individually," do you mean one
14 party at a time?

15 A. Yes, that's generally what he did, and I recall
16 that's what he did on November the 19th.

17 Q. Now, can you recall what was discussed at this
18 first mediation session as distinguished from what was
19 discussed at other ones?

20 A. I believe that I can, Mr. Nields, but let me --
21 let me hasten to add that my memory of any particular
22 mediation session may not be as precise. I have a very
23 vivid memory of the entire course of the proceedings,
24 but as to what happened at any particular session,
25 there may be some overlap in my mind.

1 To the best of my memory, what happened in this
2 meeting was Judge Reuter relayed to us what ESI
3 Lederle's settlement position was. He told us that
4 they were looking for a payment I think the order of
5 \$90 million in exchange for their agreement to stay off
6 the market during the life of the patent.

7 Q. And did you -- continue.

8 MR. EISENSTAT: Your Honor, if I may object
9 again as to the hearsay aspect of this. We now appear
10 to have double hearsay, that we now have this witness
11 recounting what a judge told him that another party
12 told them, and I'd object on hearsay grounds.

13 MR. NIELDS: Your Honor, really none of this is
14 being offered for the truth of any matter asserted.
15 What we're doing is we're finding out what the
16 mediation process was, what was communicated and what
17 people's responses were. This is the only way we can
18 prove that, and it is directly relevant to the issues
19 of the case.

20 JUDGE CHAPPELL: So, you're offering it merely
21 to show that actions were taken as a result of the
22 words and not for the truth of the matter asserted?

23 MR. NIELDS: There really is no truth of the
24 matter asserted, Your Honor. This is an offer that
25 Judge Reuter is passing on to Mr. Herman, and that is a

1 relevant fact in the case, that that offer was passed
2 on, and we offer it for that purpose.

3 JUDGE CHAPPELL: With that understanding, I'm
4 going to overrule your objection.

5 MR. EISENSTAT: Your Honor, if I may --

6 JUDGE CHAPPELL: I'm sustaining it as to the
7 truth of the matter.

8 MR. EISENSTAT: Right. If I may then make a
9 relevancy objection, that is, what this gentleman heard
10 from the judge is only relevant if the respondents are
11 going to show that the corporation heard that and then
12 acted upon it, and we understand that that's the area
13 of the -- the respondents have not allowed us to go
14 into in deposition or document discovery, and we
15 understand that's an area under your ruling that
16 they're not allowed to go into now. So, what this
17 gentleman heard is no longer relevant to the
18 respondents' case.

19 MR. NIELDS: Your Honor, this is a very odd
20 objection. The -- at issue here is what was agreed to,
21 and the way you get at that in a settlement negotiation
22 is find out what the parties said about various offers
23 and counteroffers. That's how you find out what was
24 agreed to. And Mr. Herman was -- because this was
25 court-supervised mediation, the person from Schering

1 who was doing a lot of the talking to the mediator was
2 a lawyer, but that doesn't deprive the conversations of
3 any relevance at all. This is the central way in which
4 we find out what the parties agreed to and what they
5 didn't agree to.

6 JUDGE CHAPPELL: So, Mr. Eisenstat, if I
7 understand the objection, it's not relevant because
8 it's leading to something that has been effectively
9 excluded?

10 MR. EISENSTAT: Yes, Your Honor.

11 JUDGE CHAPPELL: What's your response to that?
12 Are you getting into something that's been excluded by
13 my prior ruling?

14 MR. NIELDS: No, Your Honor, I don't plan to
15 get into anything at all that's been -- that has --
16 that any privilege claim has been asserted to at all.
17 This has been -- this has been gone into by complaint
18 counsel in deposition of Mr. Herman. They have asked
19 him about all of his conversations with Judge Reuter,
20 and he has answered all of them. No objection has ever
21 been interposed.

22 JUDGE CHAPPELL: Okay, I will overrule the
23 objection at this time.

24 MR. EISENSTAT: Very well.

25 BY MR. NIELDS:

1 Q. I think you had just told us what Judge Reuter
2 had passed on to you. What was -- did you respond?

3 A. I did, Mr. Nields. I said to Judge Reuter that
4 we weren't interested in that kind of approach. We
5 would go back -- and we weren't prepared at that time
6 to make any kind of settlement offer, but we would go
7 back and reflect on it and make an offer in due course.

8 Q. Now, I'd like you to turn to a document behind
9 tab 8. It bears SPX 76. It is dated December 10th,
10 1996. Can you identify it?

11 A. Yes. This is a letter that my partner Harris
12 Weinstein sent to Mr. Heller proposing a framework for
13 settlement by way of follow-up to our commitment to
14 Judge Reuter to reflect and propose a settlement offer
15 in due course.

16 Q. The letter reads that that framework is as
17 follows, and at the first bullet it says, "ESI will
18 provide and guarantee adequate funding of a business
19 plan reasonably designed to result in a significant
20 increase in K-Dur 20 milliequivalent market share
21 through sales of K-Dur 20 milliequivalent as agent for
22 Key."

23 Did that proposal acquire a name over time in
24 the discussions between the parties?

25 A. It certainly did. That proposal was a version

1 of what became known as co-promote or co-promotion.

2 Q. And was this proposal discussed by you with
3 counsel for ESI?

4 A. Yes.

5 Q. And what was the nature of the first discussion
6 you had?

7 A. I learned from counsel that ESI was not
8 interested in this version of co-promotion, because as
9 a generic manufacturer, they didn't have a sales and
10 detail force that was capable of selling and marketing
11 K-Dur 20.

12 Q. Was there another mediation session after the
13 initial one on the 19th of November, 1996?

14 A. Yes, there was.

15 Q. Do you remember approximately when that was?

16 A. I believe it was in February of 1997.

17 Q. And where was it?

18 A. Again, it was in Judge Reuter's chambers in the
19 courthouse in Philadelphia.

20 Q. And who was there?

21 A. To the best of my recollection, Ms. Lee was
22 there again, Mr. Driscoll was there. For ESI Lederle,
23 Mr. Heller, Ms. Somerville and Mr. Alaburda were
24 present.

25 Q. Can you describe the format at this second

1 mediation session?

2 A. Yes. Again, Judge Reuter called the parties
3 separately into his chambers and explored with us our
4 respective settlement positions and relayed to us
5 what -- his view of what the other side was proposing.

6 Q. And can you describe your discussions with
7 Judge Reuter at this -- at this mediation session?

8 A. Yes.

9 MR. EISENSTAT: Again, Your Honor, I'd like to
10 object to the hearsay nature of the conversation. We
11 have had the first meeting described where they went in
12 and they got information, and he said we could allow
13 that in because they acted upon it, and we objected on
14 the basis of relevancy, because unless we knew that he
15 told the corporation what the information was and the
16 information was acted upon, it didn't matter what this
17 man heard.

18 Now we hear that he went back, and in
19 conversations that we were not able to explore in
20 deposition, he discussed this presumably with his
21 colleagues in the corporation and come back with a
22 proposal of their own that they've now offered, and now
23 we're soliciting more hearsay to go down the same road
24 again, where they're only letting us hear what this man
25 heard, but that's not relevant with respect to what the

1 corporation did.

2 What's relevant to what the corporation did is
3 what this gentleman told the corporation and what the
4 corporation decided to do. So, I would object on
5 hearsay and relevancy grounds with respect to what this
6 witness heard the judge say.

7 MR. NIELDS: Your Honor, none of this is being
8 offered for the truth. This is all being offered to
9 show what Schering agreed to during these mediation
10 sessions and what they didn't agree to.

11 MR. EISENSTAT: We have the final agreement
12 between the parties that they've already identified, so
13 we know what the parties agreed to. There's no need to
14 offer this with respect to what the parties agreed to.
15 And it's simply irrelevant to that, what this witness
16 heard from the judge.

17 JUDGE CHAPPELL: The Government has alleged an
18 unlawful agreement.

19 MR. EISENSTAT: Yes, Your Honor.

20 JUDGE CHAPPELL: If you are going to allege an
21 unlawful agreement, then surely the intent of those who
22 supposedly formed an illegal and unlawful agreement is
23 relevant --

24 MR. EISENSTAT: Absolutely, Your Honor.

25 JUDGE CHAPPELL: -- and they -- let me finish.

1 MR. EISENSTAT: I'm sorry.

2 JUDGE CHAPPELL: -- and they have the right to
3 present that defense, but I'm not going to allow you --
4 I'm not going to allow you to try to get in the side
5 door information that you did not give up during
6 discovery. Are we clear on that?

7 MR. NIELDS: I'm certainly clear about that,
8 Your Honor. This is not side door. This is front
9 door. Mr. Herman was the agent for Schering, and he
10 was the person who was communicating with the mediator,
11 and --

12 JUDGE CHAPPELL: Well, for example, I guess an
13 example in one of the briefs, if the Government during
14 discovery asked questions about what Mr. Troup was
15 told, for example, and there was an objection, and they
16 were not allowed to know that, then I don't want to
17 hear that in this courtroom, as an example, and if Mr.
18 Eisenstat's correct -- I think he's trying to predict
19 where you're going -- that you're trying to get
20 information, you know, by side-stepping things that
21 were said to the clients, things that the Government
22 asked for and were not allowed to have, I'm not going
23 to allow that either.

24 MR. NIELDS: Your Honor, I believe the
25 following to be the case: That the conversations that

1 Mr. Herman had with the mediator and the conversations
2 that he had with opposing counsel are, A, not
3 privileged, and B, relevant to the issues in this case.
4 The complaint counsel, I think quite properly, has
5 relied throughout on what was said between the parties
6 on the subject of these settlements. That is
7 absolutely crucial evidence in a case where you're
8 trying to figure out what the parties agreed to and
9 what they didn't agree to.

10 JUDGE CHAPPELL: So, you're telling me that
11 you're not eliciting anything -- you're not eliciting
12 any information from this witness that hasn't -- that's
13 new. Nothing new.

14 MR. NIELDS: That's absolutely -- that's
15 absolutely correct, Your Honor. There may be some
16 additional detail, but I am not eliciting any
17 information that wasn't available and open to complaint
18 counsel and that complaint counsel hasn't freely
19 inquired into in their depositions.

20 They asked Mr. Herman about all of his
21 conversations with the mediator and all of his
22 conversations with ESI. No objection was ever
23 interposed. They knew it was relevant when they asked
24 those questions. It is relevant. It's absolutely
25 central to what was agreed to and what wasn't agreed to

1 by Schering-Plough.

2 JUDGE CHAPPELL: Okay, then I'm going to
3 overrule the objection at this time. I am going to
4 request complaint counsel to be a little more specific
5 if you're going to go, you know, with this line of
6 objections. I want to hear not just that I think he's
7 going into an excluded area. I want to hear objection,
8 that's something we asked for, and that's something we
9 didn't get. Is that acceptable?

10 MR. EISENSTAT: Well, if I may address that
11 point for a moment, Your Honor, when we -- Mr. Nields
12 is exactly right. We did ask about these conversations
13 in depositions, and they didn't object to it, but when
14 we asked them what did you intend by that -- as you
15 say, intent is clearly relevant -- we got the
16 objection. They wouldn't let us go beyond what they
17 said as to what the corporation was planning to do,
18 what was their intent.

19 So that all you're allowed to hear and all we
20 were allowed to hear is what this witness heard the
21 judge said and what this witness said but not what
22 decision the corporation made. So, as long as we can't
23 get at what the intent was through this evidence,
24 because they blocked us going down and asking what
25 their intent was, then this evidence becomes

1 irrelevant.

2 JUDGE CHAPPELL: Well, I think as someone said
3 earlier, we know what decision was made. We have the
4 agreement.

5 MR. EISENSTAT: Right.

6 JUDGE CHAPPELL: And I think you're stretching
7 it a little thin. I think you're misapplying it and
8 misconstruing my ruling. You know, I'm talking about
9 an area where you asked the question, and they were not
10 allowed to answer. I'm not making it -- you're casting
11 the net too wide, okay?

12 MR. EISENSTAT: Very well.

13 JUDGE CHAPPELL: You're welcome to object, and
14 we will hash it out. That's what we're here for.

15 So, with that, it's overruled, and you may
16 proceed.

17 MR. NIELDS: Thank you, Your Honor.

18 BY MR. NIELDS:

19 Q. I think my question was what was discussed
20 between you and Judge Reuter at this second mediation
21 session?

22 A. As I recall, we said to Judge Reuter that we
23 were -- we had made a co-promote proposal. Judge
24 Reuter had said to us that ESI's position remained that
25 they wanted us to make a payment. We said to Judge

1 Reuter that we weren't interested in that approach,
2 because we had antitrust concerns and because we -- we
3 were reasonably confident that we would win the case.

4 Q. And what was his response?

5 A. Judge Reuter said to us that he wanted the case
6 to settle, that Judge DuBois wanted the case to settle,
7 and he wanted us to go back and be creative and try to
8 find some creative approach that would settle the case.

9 MR. EISENSTAT: Your Honor, may we have a
10 continuing objection, then, to the hearsay testimony as
11 to what one judge said that another judge said?

12 JUDGE CHAPPELL: Continuing objections get too
13 confusing in the record. Feel free to object when you
14 want.

15 MR. EISENSTAT: Okay, then I object to the
16 witness' statement as to what one judge told him that
17 another judge said. The first judge is hearsay and the
18 second judge is double hearsay, and we object to that
19 on hearsay grounds.

20 MR. NIELDS: Once again, Your Honor, none of
21 this is being offered for the truth of any matter
22 asserted. It's being proved to show the discussions
23 with the mediator so that we can get at what was agreed
24 to and what wasn't agreed.

25 JUDGE CHAPPELL: I've allowed you a little

1 latitude here, Mr. Nields, but I don't think we need to
2 hear so much detail about what a judge said and what he
3 said to the judge. Let's cut to the chase. What was
4 he -- what did he do and why did he do it? Let's get
5 to the point rather than -- I don't need to hear
6 chapter and verse about what the judge said and what he
7 said to the judge, okay? It's not going to affect the
8 decision in the case.

9 As you say, what's important is what action was
10 taken based on these meetings. So, I don't need to
11 hear everything that was said at the meetings. And
12 I'm -- I am sustaining the objection as to the truth of
13 the matter asserted. I've established that. And I'm
14 allowing it for actions taken. They took some act
15 based on their impression of what they heard or what
16 they had to do. So, let's just try to get away from
17 everything that was said.

18 Let's proceed.

19 MR. NIELDS: Okay, Your Honor. I will try to
20 minimize that, but there are things that were said
21 between Mr. Herman and Judge Reuter that I believe will
22 be relevant to Your Honor's understanding of the course
23 of dealings, but I will try to keep it to a minimum.

24 JUDGE CHAPPELL: Proceed as you will, and we'll
25 handle the objections when they arise.

1 MR. NIELDS: Thank you, Your Honor.

2 BY MR. NIELDS:

3 Q. I'd like you to turn to a document behind tab
4 11 and ask if you can -- it's a letter dated March 12,
5 1997. It bears SPX 1198. Can you identify it?

6 A. Yes. This is a letter that Judge DuBois sent
7 to counsel telling us that he understood from Judge
8 Reuter that settlement discussions were ongoing,
9 extending some dates in the scheduling order because
10 those discussions were continuing, and expressing his
11 hope that we would arrive at a settlement.

12 Q. I'd like you now to turn to a document behind
13 tab 12. It's a letter dated March 19, 1997. It bears
14 CX 458. Can you identify it?

15 A. Yes. This is a letter that I received from Mr.
16 Heller telling me that he had been advised that our
17 co-promotion proposal entailed considerable antitrust
18 risks.

19 Q. And was there discussion between the parties
20 regarding this letter?

21 A. Yes, following the letter, I called Mr.
22 Heller --

23 Q. That --

24 A. Yes.

25 Q. That's fine. We're going to move along.

1 If you go to the document behind tab 13, you'll
2 find a letter dated April 18, 1997. It bears Exhibit
3 Number CX 459. Can you identify it?

4 A. Yes. This is a letter that I sent to Judge
5 Reuter on behalf of both ESI Lederle and Key reporting
6 on the state of our settlement efforts and reporting
7 that those efforts were then at a standstill.

8 Q. And did the efforts remain at a standstill for
9 some period of time?

10 A. They did until relatively late in the summer of
11 1997.

12 Q. And did the mediation process pick up again in
13 the summer of 1997?

14 A. Yes, Mr. Nields, I believe it was in August of
15 1997.

16 Q. And what brought that about?

17 A. Judge DuBois convened a conference call with
18 counsel and urged us to return to mediation with Judge
19 Reuter.

20 Q. And if you go to the document behind tab 14,
21 you'll find a letter dated July 25th, 1997. It bears
22 CX 462. Can you identify that?

23 A. Yes. This is a letter that I wrote to Judge
24 DuBois on behalf of both ESI Lederle and Key reporting
25 on the status of settlement in response to his order of

1 July 6th asking us to submit a settlement report.

2 Q. And it states at the end of it that Key will be
3 prepared to begin meeting with Judge Reuter during the
4 week of August 18 after counsel returns from vacation.

5 A. Yes.

6 Q. And was there a mediation session with Judge
7 Reuter the week of August 18?

8 A. Yes, there was. I believe it was August 20th,
9 Mr. Niels.

10 Q. And where was that?

11 A. It was again in Judge Reuter's chambers in the
12 courthouse in Philadelphia.

13 Q. Who was present for that?

14 A. At that meeting, again, I was there, Ms. Lee
15 was there, a business person from Key Pharmaceuticals
16 by the name of John Wasserstein was there, and Ray
17 Kapur was there, who was the head of the generic
18 division of Schering-Plough called Warrick.

19 For ESI Lederle, Dr. Dey was there, Mr.
20 Alaburda was there, Mr. Heller was there and I believe
21 his colleague Ms. Somerville was there.

22 Q. And can you describe the format of that
23 mediation session?

24 A. Yes. As I recall, in that session we began
25 with a joint meeting in Judge Reuter's chambers --

1 excuse me, Judge Reuter's courtroom, and then after a
2 while adjourned to his chambers, again each party
3 separately meeting with the judge.

4 Q. I think you said that your partner Mr. Rule was
5 there?

6 A. He was.

7 Q. And did Mr. Rule at some point during the
8 proceedings address antitrust issues with Judge Reuter?

9 A. Yes. Mr. Rule, who was prior to rejoining
10 Covington & Burling head of the Antitrust Division of
11 the Justice Department, expressed his view that the
12 approach suggested by ESI Lederle -- that is, a payment
13 in exchange from Key in exchange for not going on the
14 market -- entailed antitrust concerns.

15 Q. And was there a response on that subject by
16 Judge Reuter?

17 A. There was. Judge Reuter said that that
18 surprised him because he and Judge DuBois would be
19 approving the settlement. He couldn't understand how
20 there could be real antitrust issues.

21 Q. And did Mr. --

22 MR. EISENSTAT: Again, Your Honor, I would like
23 to object on hearsay and move to strike that answer.
24 Again, we have hearsay -- double hearsay where this
25 witness is reporting an out-of-court conversation with

1 one judge about what a second judge discussed with that
2 first judge.

3 MR. NIELDS: Your Honor, again, this has been
4 inquired into by complaint counsel freely with several
5 witnesses, and it is being offered because it is an
6 important aspect of what Schering agreed to and what it
7 didn't agree to.

8 MR. EISENSTAT: It's -- and I didn't hear him
9 say it was not being offered for the truth, though,
10 Your Honor.

11 MR. NIELDS: I've said that several times, and
12 it's a -- kind of a standing statement, that it is not
13 being offered for the truth. It's being offered to
14 prove the course of the negotiations, Your Honor, and
15 as you know from our brief, we believe that the fact
16 that Judge Reuter approved this settlement after
17 antitrust issues had been discussed with him makes the
18 approval more significant.

19 MR. EISENSTAT: And it also makes it sound like
20 they're offering it for the truth of the matter stated,
21 that is, the judge saying I'm going to approve this.
22 That doesn't sound like they're offering it for any
23 other purpose, Your Honor.

24 JUDGE CHAPPELL: Is there better evidence of
25 this? Is there a -- is there a certified transcript of

1 a hearing or a --

2 MR. NIELDS: There is not, Your Honor.

3 JUDGE CHAPPELL: At any point?

4 MR. NIELDS: At any point.

5 JUDGE CHAPPELL: If it's not being offered for
6 the truth, why do I need to hear that Judge Reuter said
7 he and Judge DuBois would be approving this settlement,
8 he couldn't understand how there would be a real
9 antitrust issue?

10 MR. NIELDS: Well, there is more to the
11 conversation. There's the response to that, which we
12 believe is relevant. We believe, Your Honor, that
13 Schering's discussions with Judge Reuter on the subject
14 of a settlement involving a significant payment to ESI
15 is directly responsive to the case that complaint
16 counsel has brought.

17 JUDGE CHAPPELL: So, you're saying whether
18 Judge DuBois and Judge Reuter understood it or not
19 doesn't matter, but they said it, and that's why you're
20 offering it, because it was said. Is that right?

21 MR. NIELDS: Yes, Your Honor, I'm offering it
22 because it was said.

23 JUDGE CHAPPELL: Overruled.

24 BY MR. NIELDS:

25 Q. And I think you -- I think you were about to

1 give us what -- I think you testified that Judge Reuter
2 indicated what's the problem if he was approving it,
3 and did Mr. Rule make a response?

4 A. Yes, Mr. Rule replied that in his view that
5 would be helpful but not dispositive.

6 Q. And at the end of the session, had there been
7 any agreement to settle on any terms?

8 A. No.

9 Q. I'd like you to turn now to a document behind
10 tab 19. It is SPX 94, and it is -- if you turn to the
11 third page of that exhibit, it's a letter dated
12 September 24, 1997. Can you identify it?

13 A. Yes. This is a letter that Mr. Heller had sent
14 to me following the mediation conference showing the
15 amount of profits that ESI Lederle believed that it
16 would garner if it were to win the case.

17 Q. I'd like you to turn to a document behind tab
18 20. It bears CX 465, and if you turn to the second
19 page, it's a letter dated October 14, 1997 from Michael
20 Dey to Ray Kapur. Can you identify it?

21 A. Yes. This is a letter that Dr. Dey wrote to
22 Mr. Kapur discussing a proposal to license several
23 products to the Warrick division of Schering-Plough for
24 overseas sale.

25 Q. And are those products enalapril and buspirone?

1 A. Yes.

2 Q. Now, was there another mediation session after
3 the one in August?

4 A. Yes, Mr. Nields, I believe it was in October
5 was the next one.

6 Q. And where was that one?

7 A. Again, in Judge Reuter's chambers in the
8 courthouse in Philadelphia.

9 Q. And who was present for that?

10 A. At that session, I believe that -- again, Mr.
11 Kapur was present, Mr. Wasserstein was present. I
12 can't recall for certain whether Ms. Lee was present.
13 And in addition, for Key Pharmaceuticals, John Hoffman
14 was present, and Mr. Hoffman is vice president and
15 assistant general counsel of Schering in charge of
16 litigation and is an antitrust lawyer.

17 Q. Was there further discussion of some of the
18 same issues that had been discussed earlier?

19 A. Yes, there was.

20 Q. And was there any agreement at the end of that
21 mediation session?

22 A. No.

23 Q. Was there a discussion about -- between
24 Schering and Judge Reuter about an issue involving
25 ESI's approvability of its product?

1 A. Yes.

2 Q. Can you describe that discussion?

3 A. Yes. I said to Judge Reuter that we had become
4 very puzzled by the fact that ESI Lederle's ANDA for
5 its generic product had not been approved given the
6 considerable length of time that had gone by, and we
7 were now skeptical whether that approval would ever be
8 forthcoming and whether, in fact, ESI Lederle had an
9 approvable product.

10 Q. Okay, I'd ask you to turn to a document behind
11 tab 23. It is a letter dated November 12th, 1997. It
12 bears CX 468. Can you identify it?

13 A. Yes. It's a letter that I sent to Judge Reuter
14 expressing our position that it would be a waste of the
15 Court's and the parties' time to go forward with a
16 settlement conference that had been scheduled I think a
17 week later in November.

18 Q. And was that conference that had been scheduled
19 in November eventually put off?

20 A. It was, yes.

21 Q. Now, the second paragraph of the letter says,
22 "As you may recall, at our last settlement conference,
23 ESI stated that it would reconsider the possibility of
24 a settlement concept incorporating a co-promote of
25 Key's potassium chloride product between the two

1 companies," and then at the bottom of that paragraph,
2 it says, "On Monday, November 10th, ESI informed me
3 that it has again decided it is unwilling to agree to
4 such a structure, citing antitrust concerns."

5 Do you see that?

6 A. I do.

7 Q. And had ESI -- had their -- had the opposing
8 counsel from ESI told you that they were no longer
9 interested in a co-promote?

10 A. Yes.

11 Q. And was that the last time the co-promote
12 concept came up?

13 A. Yes, it was, Mr. Nields.

14 Q. Now, on the top of page 2, it says, "In
15 addition, on Monday, Key renewed its request to review
16 ESI's correspondence with the FDA so that Key can
17 satisfy itself that ESI has a potentially marketable
18 product. As we discussed --" at the bottom of that
19 paragraph, it says, "As we discussed during the last
20 settlement conference, Key is unwilling to make another
21 settlement offer until ESI demonstrates that it has a
22 bona fide 20 milliequivalent potassium chloride product
23 that but for this lawsuit would receive FDA approval."

24 Do you see that?

25 A. I do.

1 Q. And did you eventually get some information
2 from ESI Lederle about that issue?

3 A. Yes. Mr. Heller and Ms. Somerville sent me
4 some correspondence that they had had with FDA and
5 communicated to me the current -- their view of the
6 current status of the -- ESI Lederle's effort to gain
7 approval of their ANDA.

8 Q. And I'd ask you to turn to a document behind
9 tab 27. It is a letter dated December 15, 1997. It
10 bears CX 469. Can you identify it?

11 A. Yes. This is a letter that I wrote to Mr.
12 Heller and Ms. Somerville attaching a summary of the
13 information that they had provided regarding the status
14 of FDA approval that I had proposed sharing with the
15 business people at -- at my client.

16 Q. I'm going to -- reading from the beginning of
17 the second paragraph, the letter says or your summary
18 says, "The first problem involved an in vivo study
19 included in the ANDA to demonstrate that Micro-K 20 is
20 bioequivalent to K-Dur 20."

21 Micro-K 20 was ESI's product?

22 A. Yes, it was.

23 Q. It goes on, "The study, which was performed in
24 1989, measured among other things the amount of KCl in
25 the urine of 30 patients taking Micro-K 20 or K-Dur

1 20," and then it says, "In a letter dated June 27,
2 1996, the Division of Bioequivalence of the Office of
3 Generic Drugs at the FDA asserted five different
4 deficiencies with regard to the study."

5 And at the top of the next paragraph, it says,
6 "Almost a year later, in a letter dated May 14, 1997,
7 ESI responded to the deficiencies identified in the
8 bioequivalence study."

9 At the beginning of the next paragraph, it
10 says, "In a letter dated August 6th, 1997, the Division
11 of Bioequivalence rejected ESI's response."

12 At the beginning of the next paragraph, it
13 says," ESI's ANDA cannot be approved without an
14 adequate bioequivalent study, however, and it appears
15 that ESI is now undertaking a new bioequivalent study."
16 At the end of that paragraph it says, "ESI's outside
17 counsel had represented that, 'We believe clinical
18 trials relating to bioequivalence were started on
19 December 8th, 1997.'"

20 That was one week before the date of your
21 letter?

22 A. Yes, it was.

23 Q. All right, I'd like you to turn -- following
24 that -- receiving that information, did Key make an
25 actual offer to compromise the lawsuit?

1 A. Yes, we did.

2 Q. And turning to tab -- the document behind tab
3 28, there is a letter dated December 17, 1997. It
4 bears exhibit number CX 470. Can you identify it?

5 A. Yes. It's a letter that I sent to Mr. Heller
6 transmitting a settlement offer on behalf of my client.

7 Q. And it states, "Dear Paul," that's Mr. Heller?

8 A. That is Mr. Heller.

9 Q. "We propose to settle the case based on the
10 following: One, Schering shall grant ESI a
11 royalty-free license under the '743 patent to make,
12 use, offer for sale and sell its Micro-K 20 potassium
13 chloride product in the United States effective
14 December 31, 2003. Until that date, ESI shall not
15 make, use, offer for sale or sell its Micro-K 20
16 product."

17 Do you see that?

18 A. I do.

19 Q. How does the date in that letter, December 31,
20 2003, compare to the date that was agreed to in the
21 final agreement?

22 A. It's one day off. In the final agreement, the
23 agreed-upon date was January 1st, 2004.

24 Q. Then two, it says, "ESI will acknowledge
25 infringement and validity of the '743 patent in a

1 consent judgment."

2 And then below that there's an unnumbered
3 paragraph that says, "As an additional matter, ESI
4 shall grant Schering, including its designees,
5 exclusive licenses for buspirone, enalapril and three
6 other products under development by ESI to be mutually
7 agreed upon by the parties."

8 Then over to the next page, it says, "In
9 exchange for the licenses described in the unnumbered
10 paragraph above, Schering shall pay ESI an up-front
11 payment of \$5 million and a 5 percent royalty on annual
12 sales for ten years post-approval."

13 Did ESI respond?

14 A. It did.

15 Q. And if we turn to tab 29, you will find a
16 letter dated December 22, 1997 bearing exhibit number
17 CX 473. Can you identify that?

18 A. Yes. That's Mr. Heller's response.

19 Q. Now, it reads, "The general structure --"

20 MR. EISENSTAT: Your Honor, may I object?
21 We've been hearing counsel for respondent read the
22 documents into the record. The documents are already
23 in the record. I don't hear any questions, though,
24 going to the witness. If he wants to ask questions to
25 the witness, we should proceed by Q and As.

1 MR. NIELDS: Your Honor, the document is in
2 evidence, and perhaps I should say some of the time,
3 "Your Honor, may I publish this document?" I believe
4 that the testimony will be more easily understandable
5 if I do so, but I'm about to ask him some questions
6 about this document, and I didn't get the question out
7 because Mr. Eisenstat objected.

8 JUDGE CHAPPELL: Mr. Eisenstat, I agree with
9 you that it's unnecessary to read from a document
10 that's in evidence; however, I think everyone here
11 knows that ship has sailed in this case. Mr. Nields
12 can proceed with his case as he chooses. That's why
13 we're here. So, I'm overruling the objection.

14 MR. EISENSTAT: Very well, Your Honor.

15 BY MR. NIELDS:

16 Q. The letter says, "Dear Tony: The general
17 structure of your December 17 proposal is acceptable
18 with the following modifications." Then he says, "The
19 effective date of the license under the '743 patent
20 should be December 31, 2003, or whenever a generic is
21 placed on the market, whichever occurs earlier."

22 How does that compare with Key's offer?

23 A. The December 31st, 2003 date is the same, but
24 the "whenever a generic is placed on the market,
25 whichever occurs earlier" was different.

1 Q. All right. Then the next paragraph says, "ESI
2 Lederle will acknowledge validity and enforceability
3 but not infringement."

4 How does that compare to Schering's -- Key's
5 offer?

6 A. Key had proposed that they acknowledge
7 infringement as well.

8 Q. And then the next paragraph reads, "ESI Lederle
9 agrees to grant Schering licenses," it goes on, "for
10 buspirone, enalapril and three other products to be
11 agreed on in good faith," and then skipping to the end
12 of the letter, it says, "The initial up-front payment
13 of \$5 million will be followed by further payments upon
14 the issuance by the FDA of an approvable letter for ESI
15 Lederle's ANDA and thereafter for a total of \$55
16 million, the time schedule to be agreed on by the
17 parties."

18 How does that differ from Key's offer?

19 A. The difference there is the \$55 million.

20 Q. Was it actually a \$50 million difference?

21 A. Yes, it's a \$50 million difference.

22 Q. Then he says, "The royalty rate for the
23 licenses to Schering will be 50 percent of gross
24 profit."

25 Does that differ from Schering's offer?

1 A. Yes, Schering had proposed 5 percent of annual
2 sales.

3 Q. Was there another mediation session after this
4 exchange of letters?

5 A. Yes, in conjunction with the Markman hearing
6 held before Judge DuBois around January 21st and 22nd.

7 Q. What is a Markman hearing?

8 A. A Markman hearing is a hearing at which
9 evidence is taken, argument is heard, so the Court can
10 interpret the claims of the patent at issue in the
11 lawsuit.

12 Q. Do you remember the -- how many mediation
13 sessions there were during the week of the Markman
14 hearing?

15 A. My best memory is that there were two, one on
16 the 22nd of January and another one the 23rd. My
17 memory of precisely what transpired on the 22nd is
18 rather dim. I have quite a vivid memory of what took
19 place on January the 23rd.

20 Q. And was January 23rd the meeting where there
21 was actually an agreement reached?

22 A. An agreement in principle was reached, yes.

23 Q. How did -- going to that meeting that you have
24 a memory of, how did that come about, that mediation
25 session?

1 A. Judge DuBois summoned Mr. Heller and me into
2 chambers and said to us that the Markman hearing had
3 concluded, that was all well and good, and now he
4 wanted us to go up and see Judge Reuter and settle the
5 case.

6 Q. And did you have a response?

7 A. I did. I said to Judge DuBois that I had a
8 pressing family matter to attend to in Washington and
9 needed to return home that evening and consequently
10 would strongly prefer to put off the settlement
11 conference until perhaps Monday, and Judge DuBois said
12 to me, no, Mr. Herman, it's too late for that. You're
13 going to go up and see Judge Reuter, and you're going
14 to stay in the courthouse until the case is settled.

15 MR. EISENSTAT: Objection, Your Honor, hearsay.

16 MR. NIELDS: Your Honor, we're revisiting old
17 ground. There is no truth of the matter asserted.
18 We're putting that in to show that was said to Mr.
19 Herman that caused him to go speak with Judge Reuter.

20 JUDGE CHAPPELL: I agree that you're offering
21 it because it was said, not because it's true; however,
22 it's a great deal more detail than we need. I don't
23 need to know the reasons he told the judge he didn't
24 want a hearing. I just need to know that he requested
25 a delay and was told to get upstairs or whatever at

1 this time.

2 So, I'm overruling the objection, but I'm just
3 letting you know, we're still -- we're going into
4 things we don't need to get into. We just don't need a
5 recitation of everything that's said in these meetings.
6 I mean, you've conceded that you're trying to make the
7 point that things were said and people acted upon what
8 was said.

9 MR. NIELDS: Yes, Your Honor.

10 JUDGE CHAPPELL: Not because it's true. So, I
11 think you'll agree with me, we don't need as much
12 detail as we just heard in that last answer.

13 MR. NIELDS: I apologize, Your Honor. I
14 understand we are now getting to the meeting at which
15 the settlement was actually arrived at, and I will be
16 asking him some questions about that.

17 JUDGE CHAPPELL: Okay.

18 BY MR. NIELDS:

19 Q. Did you then go and have a meeting with Judge
20 Reuter?

21 A. I did.

22 Q. And can you -- approximately what time was it?

23 A. I recall it was about 5:30 in the evening that
24 we first went up to see Judge Reuter that day.

25 Q. And how long was the session?

1 A. It concluded around 11:30 at night.

2 Q. And can you set the scene in terms of who was
3 there, who participated and where the people who
4 participated were?

5 A. Yes. Of course, Judge Reuter was there. For
6 Schering, Ms. Lee and I were there. For ESI Lederle,
7 Mr. Heller was there and at least for part of the time
8 Dr. Dey was there, and I believe Mr. Alaburda was there
9 most if not the entire -- most of the time if not the
10 entire time, and there were phone calls between Judge
11 Reuter and John Hoffman at home and Marty Driscoll, who
12 was at a Nets basketball game with his child and a
13 friend of his child.

14 Q. And again, without getting into a huge amount
15 of detail, can you summarize what was discussed and
16 what was agreed to?

17 A. Yes. By that time, the license agreement was
18 in place, it had already been agreed to. The amount of
19 money that Schering would pay for the license was
20 fixed. The --

21 Q. At how much?

22 A. My best memory is it was \$15 million. The date
23 of market entry of ESI Lederle's generic product was
24 also fixed going into the meeting.

25 Q. And is that the January 1, 2004 date?

1 A. January 1, 2004, yes.

2 Q. Okay. So, what was discussed then? What was
3 negotiated?

4 A. ESI Lederle was insisting on additional
5 payments, and I took the position initially that we
6 weren't going to pay any more money. We wanted to try
7 the case. Judge Reuter then said, well, why don't you
8 give him \$5 million, that really is nothing more than
9 legal fees, and when I said no to that, he called Mr.
10 Driscoll -- he asked me if he could call Mr. Driscoll
11 and Mr. Hoffman. I said of course he could, and he
12 did.

13 MR. EISENSTAT: Objection again, Your Honor, on
14 the hearsay as to what the judge said.

15 MR. NIELDS: Your Honor, we're revisiting old
16 ground. We're not offering it for the truth. We're
17 just offering it for the fact that it was said, and I
18 think we're about to hear Schering's response.

19 MR. EISENSTAT: I think the truth of the matter
20 that they're offering it for is that the judge said it.
21 That's -- their allegation here is that the judge told
22 them to make this offer, and I think that's what
23 they're offering it for.

24 JUDGE CHAPPELL: And if he has agreed with me
25 it's not being offered for that, then it's not going to

1 be used for that when the record is reviewed in this
2 case, Mr. Eisenstat.

3 MR. EISENSTAT: Very well, Your Honor.

4 JUDGE CHAPPELL: And we are getting into an
5 area -- I'm overruling the objection, but we're getting
6 into what I would call operative facts. There is an
7 agreement that's alleged to be unlawful. This witness
8 seems to be someone who was there. Maybe it is, maybe
9 it's not hearsay. There are a million exceptions, and
10 we're hashing them out as we go.

11 I don't think anybody wants to subpoena Judge
12 Reuter or Judge DuBois, and they're trying to defend
13 themselves. So, I'm allowing some latitude in that
14 regard.

15 You may proceed.

16 MR. NIELDS: Thank you, Your Honor.

17 BY MR. NIELDS:

18 Q. I think you were saying that Judge Reuter
19 called Mr. Hoffman and Mr. Driscoll and proposed that
20 they pay -- agree to pay \$5 million, which he
21 characterized as --

22 A. He said it was like their legal fees.

23 Q. And was there eventually an agreement by
24 Schering to do that?

25 A. Yes, there was.

1 Q. And was there any other issue that came up that
2 became important to the settlement?

3 A. Yes. ESI was insisting on another \$10 million.
4 Mr. Hoffman replied, why would we give them any more
5 money when they don't even have a product? Judge
6 Reuter said, well, if you're so sure they don't have a
7 product, just put your money where your mouth is and
8 let's do this in the form of a bet, and if they don't
9 have a product, we'll structure it so it won't cost you
10 a dime.

11 And Judge Reuter then proposed a term by which
12 there was a sliding scale payment from \$10 million to
13 zero depending on when and if ESI got FDA approval.

14 JUDGE CHAPPELL: Mr. Herman, excuse me, you're
15 a practicing attorney, right?

16 THE WITNESS: I am, yes.

17 JUDGE CHAPPELL: Then you well understand that
18 when an attorney stands up to object, you need to stop
19 your answer.

20 THE WITNESS: Yes, sir.

21 JUDGE CHAPPELL: Thank you.

22 Mr. Eisenstat?

23 MR. EISENSTAT: Objection on the hearsay
24 grounds again, more as to what Judge Reuter said. Now
25 we're getting into their claim that it was the judge

1 that suggested this whole structure that we allege is
2 illegal, and this evidence I don't believe is competent
3 with respect to that. As you say, no one wants to call
4 the magistrate judge or the judge, but if they want to
5 get into evidence what they said in an out-of-court
6 statement, I believe they have to, Your Honor.

7 JUDGE CHAPPELL: Well, if what this witness is
8 saying is hearsay, what the judges said at the same
9 meeting would be the same hearsay.

10 MR. EISENSTAT: Well, we could question the
11 judge, Your Honor. We can't question the judge when
12 this witness represents what the judge said. What's
13 the difference?

14 JUDGE CHAPPELL: Are you offering it, as you
15 have been, just the fact that the statements were made,
16 not for the truth of the matter?

17 MR. NIELDS: I'm offering it exactly as I have
18 been, Your Honor, and I would submit that Mr. Herman is
19 competent to testify directly to what Judge Reuter said
20 and that what Judge Reuter said is relevant. It is
21 very, very important to our case. They may not like
22 the fact that there is direct evidence that Judge
23 Reuter suggested this term and approved it, but there
24 is direct evidence to that effect, and we're presenting
25 it through Mr. Herman. It bears directly, Your Honor,

1 on Schering's purpose and reasons for entering into
2 this agreement.

3 JUDGE CHAPPELL: What he said, if I've been
4 following you, is not why you're offering it. You're
5 not offering it for what he said. You're offering it
6 for the fact the statement was made. Is that correct?

7 MR. NIELDS: I believe that's right, Your
8 Honor.

9 JUDGE CHAPPELL: And with that understanding,
10 I'll overrule the objection.

11 BY MR. NIELDS:

12 Q. And did Schering eventually agree to that term?

13 A. We did, Mr. Nields.

14 Q. Now, how was the -- and did that mean that
15 there was an agreement in principle?

16 A. Yes.

17 Q. And how was it documented again?

18 A. We were in the secretarial area of Judge
19 Reuter's chambers, and Mr. Heller handwrote out the
20 settlement principles with all of us sort of clustered
21 around him.

22 Q. Now, turning back to that document, which is
23 Exhibit 34, do you have that in front of you?

24 A. I do, sir.

25 Q. Excuse me, not Exhibit 34, it's behind tab 34.

1 It's Exhibit CX 472.

2 And my question is this: Is this agreement
3 complete in terms of representing what the parties
4 agreed to that night?

5 A. It is not complete in that it doesn't allocate
6 the money payments as to -- as between the license
7 agreement and the \$5 million payment.

8 Q. When you say the "license agreement," you mean
9 the one for buspirone and enalapril?

10 A. Yes, I do.

11 Q. Now, was a more formal agreement prepared
12 later?

13 A. Yes, initially a draft agreement was sent to us
14 by Mr. Heller's colleague Deborah Somerville.

15 Q. And that was the first draft of the formal
16 agreement?

17 A. Yes.

18 Q. And turn to the document behind tab 37. You'll
19 see a cover letter dated February 9, 1998 and an
20 exhibit number CX 478. Can you identify that?

21 A. Yes. This is a copy of the transmittal letter
22 from Deborah Somerville to my partner Paul Berman
23 forwarding the initial draft agreement.

24 Q. And does that initial draft agreement
25 accurately reflect what the parties agreed to that

1 night with Judge Reuter?

2 A. It does not.

3 Q. And in what respect does it not?

4 A. It in paragraph 16 characterizes all the
5 payments as royalty payments, when, of course, only \$15
6 million of the \$30 million were royalty payments, in
7 fact.

8 Q. And was that corrected in the final drafts of
9 the agreements?

10 A. Yes, it was.

11 Q. And who did the final drafts?

12 A. Covington & Burling prepared the final drafts.

13 Q. And I'd ask you to turn to documents behind tab
14 39 and behind tab 40. Can you identify -- let's see,
15 the one behind 39 is an agreement dated -- bearing the
16 exhibit number CX 480.

17 A. Yes, that's a copy of the final license
18 agreement that was agreed to.

19 Q. The license agreement being the one for
20 enalapril and buspirone?

21 A. Yes.

22 Q. And if you'd turn behind tab 40, you'll find a
23 document marked CX 479.

24 A. This is a copy of the agreement settling the
25 lawsuit.

1 MR. NIELDS: Your Honor, I have no further
2 questions.

3 JUDGE CHAPPELL: Okay.

4 MR. EISENSTAT: May I have a few minutes, Your
5 Honor, before I start my cross examination?

6 JUDGE CHAPPELL: Yes, you may. In fact, it's
7 after 4:00. This should be a good time for a break.
8 Let's recess until 4:20. Thank you.

9 (A brief recess was taken.)

10 JUDGE CHAPPELL: Does complaint counsel have
11 any cross?

12 MR. EISENSTAT: Yes, Your Honor.

13 JUDGE CHAPPELL: You may proceed.

14 CROSS EXAMINATION

15 BY MR. EISENSTAT:

16 Q. Mr. Herman, you were lead counsel for Schering
17 in the litigation between Schering and ESI. Is that
18 correct?

19 A. For most of the time, yes.

20 Q. Did you also work on the litigation between
21 Schering and Upsher-Smith?

22 A. I did.

23 Q. Were you lead counsel in that case?

24 A. For most of the time.

25 Q. That case settled prior to the ESI case, did it

1 not?

2 A. Yes.

3 Q. And were you going to be -- were you actually
4 going to try the case before the judge there? Were you
5 going to be the lead trial counsel?

6 MR. NIELDS: Your Honor, we seem to be getting
7 into the Upsher-Smith case, which is way beyond the
8 scope of direct. There will be -- this witness has
9 testified solely about the ESI case.

10 MR. CURRAN: Same objection, Your Honor.

11 MR. EISENSTAT: If I may have a little
12 latitude, Your Honor, I'm just laying a foundation to
13 go into the relationship between the settlement of the
14 Upsher-Smith case and the settlement of the ESI case.
15 He's testified how he perceived the ESI case settling.
16 I think they left out a fact about the Upsher-Smith
17 case. I'm just laying a foundation that he's
18 knowledgeable so I can bring that out.

19 JUDGE CHAPPELL: So, you're attempting to lay a
20 foundation for impeachment?

21 MR. EISENSTAT: Yes, Your Honor.

22 JUDGE CHAPPELL: I'll allow it, overruled, but
23 I'm not going to allow the same questions on cross
24 after Upsher-Smith questions the witness. You may
25 proceed.

1 MR. EISENSTAT: Fine, very well.

2 BY MR. EISENSTAT:

3 Q. You were actually going to try that case?

4 A. You're asking me whether I was lead counsel,
5 Mr. Eisenstat?

6 Q. Yeah, were you actually going to do the trial
7 in front of the judge?

8 A. I would have been the lead trial lawyer, yes.

9 Q. At some point in time, ESI found out about the
10 settlement in the Upsher-Smith/Schering case?

11 A. It did.

12 Q. And they requested a copy of the settlement?

13 A. They did.

14 Q. And initially Schering refused to give them a
15 copy of that settlement?

16 A. Yes.

17 Q. And there was a motion made before the judge
18 to -- by ESI to obtain that settlement?

19 A. That's correct, yes.

20 Q. And the judge ordered you to turn that
21 settlement over to ESI?

22 A. Yes, he did.

23 Q. Do you recall approximately when that
24 settlement was turned over to ESI?

25 A. No, I really don't, sir, I'm sorry.

1 Q. Do you have any recollection at all as to the
2 time?

3 A. I really -- I really don't, no, I'm sorry.

4 Q. After you turned the settlement over to the --
5 or did you turn the settlement over to the ESI
6 attorneys?

7 A. Yes, we did.

8 MR. CURRAN: Objection, Your Honor. This is
9 not impeachment. This is adducing facts related to the
10 Upsher-Smith/Schering settlement agreement.

11 MR. EISENSTAT: Again, Your Honor, I'm laying a
12 foundation to show that a fact they left out of this
13 story of the ESI-Schering settlement was the fact that
14 ESI knew about the settlement and knew about the
15 structure of the settlement with Upsher-Smith before
16 they went into these negotiating sessions that counsel
17 testified about in October and January.

18 JUDGE CHAPPELL: Mr. Curran, does Upsher-Smith
19 intend to direct examine this witness?

20 MR. CURRAN: Your Honor, my understanding is
21 that this witness will be coming back later in the
22 case -- am I correct -- oh, I'm sorry. No, Your Honor,
23 Upsher-Smith does not intend to examine this witness.

24 JUDGE CHAPPELL: So, your objection is beyond
25 the scope?

1 MR. CURRAN: Yes, Your Honor. This witness was
2 designated to appear today to testify on the
3 ESI-Schering settlement, and that's all he was
4 questioned about in his direct examination. Mr.
5 Eisenstat is going beyond the scope of that.

6 JUDGE CHAPPELL: Well, the scope of impeachment
7 is not limited by what was said on direct, and based on
8 the representation that he's going to connect this up
9 as impeachment, I'll overrule the objection at this
10 time, but you may renew it later if you need to.

11 MR. CURRAN: Thank you, Your Honor.

12 BY MR. EISENSTAT:

13 Q. After you turned over a copy of the settlement
14 to counsel for ESI, was a summary of that settlement
15 created to be given to ESI's management?

16 A. Yes, I believe that's right.

17 Q. And did you approve of that settlement and the
18 turning over of that settlement to the ESI management?

19 A. Yes.

20 MR. EISENSTAT: If I may approach, Your Honor?

21 JUDGE CHAPPELL: Yes.

22 BY MR. EISENSTAT:

23 Q. I'd like to hand you what's been marked as
24 CX 464, which is a document that has been admitted into
25 evidence.

1 Do you recognize this document, sir?

2 A. I'd like a minute to read it, please.

3 Q. Yes.

4 A. (Document review.) Well, I recall the fact of
5 the document. I recall -- I mean, it's certainly my
6 signature. I'm certain I sent it to Mr. Heller.
7 Truthfully, I don't recall the substance of the
8 document.

9 Q. You don't recall the substance of the agreement
10 you reached?

11 A. Not today I don't, no. I'm -- if I could take
12 time to read it, perhaps it would refresh my memory. I
13 don't know.

14 Q. Do you want to take a moment?

15 A. If you would like me to, of course.

16 Q. Yes, please.

17 A. (Further document review.)

18 Q. Does this refresh your recollection as to the
19 substance of the agreement you reached with the ESI
20 attorneys?

21 A. I'm certain this is what was prepared. I
22 recall a document being prepared. I'm certain this is
23 the document.

24 Q. Does this refresh your recollection as to
25 approximately when the agreement was turned over to the

1 ESI attorneys and the subsequent summary was turned
2 over to the ESI management?

3 A. Well, my letter to Mr. Heller is dated
4 September the 12th, 1997, and I would assume it was
5 sometime around then.

6 Q. Do you know if the agreement was carried out,
7 that, in fact, they turned the summary of the
8 Upsher-Smith/Schering management -- that is counsel to
9 ESI turned the summary of the Upsher-Smith/Schering
10 settlement over to the ESI management?

11 A. I may have known at the time. I don't know
12 today. I don't recall. I can't imagine they didn't,
13 but I don't know that.

14 Q. And this was turned over to -- the actual
15 Upsher-Smith/Schering settlement agreement was turned
16 over to counsel for ESI before the October settlement
17 conference and before the January settlement
18 conference?

19 A. My cover letter to Mr. Heller certainly makes
20 that clear, yes.

21 Q. Going to the January meeting, you said that was
22 coincidental with the Markman hearing. Is that right?

23 A. I said it was in conjunction with the Markman
24 hearing.

25 Q. In conjunction with the Markman hearing. The

1 Markman hearing you said was a proceeding where both
2 sides put on evidence and made argument?

3 A. That's right, yes.

4 Q. Was there a transcript kept of the Markman
5 hearing?

6 A. Yes, there was.

7 Q. Were arguments ever held on the -- at the
8 Markman hearing?

9 A. There were a variety of arguments made during
10 the course of the hearing. There were opening
11 statements, I recall that.

12 Q. Do you recall if there were closing arguments?

13 A. I don't recall one way or the other. I don't
14 know.

15 Q. Do you recall if the judge wanted to hear
16 closing arguments?

17 A. I don't have a detailed memory, no, one way or
18 the other.

19 Q. Okay. You said you had two meetings you
20 believe with the magistrate judge during that time
21 period. Is that right?

22 A. I believe so, Mr. Eisenstat. I know there was
23 a meeting on Thursday, there was a meeting on Friday.
24 I think that's right.

25 Q. Do you recall coming back after the meeting on

1 Thursday, the meeting with the magistrate judge, and
2 telling Judge DuBois that you had made progress on the
3 settlement and you wanted to put off the closing
4 arguments on the Markman hearing?

5 A. No, I don't recall telling Judge DuBois that.

6 Q. Do you recall telling the judge that you wanted
7 to meet with Judge Reuter the next day, that Friday?

8 A. I recall Judge DuBois telling us that he wanted
9 us to meet with Judge Reuter. I don't recall
10 expressing my interest in meeting with Judge Reuter.
11 To the contrary, I recall that I needed to go home, and
12 I didn't want to meet with Judge Reuter on Friday.

13 Q. Do you recall the judge offering to have oral
14 arguments on the Markman hearing on that Saturday if
15 that allowed you to meet with Judge Reuter?

16 A. I do have a vague memory of that being an
17 option, yes. That does ring a bell now that you've
18 mentioned it, yes, sir.

19 Q. Do you recall Judge -- is it DuBois?

20 A. It's DuBois, sir.

21 Q. DuBois?

22 A. Yes.

23 Q. I'm bad with pronouncing names, so I apologize
24 to him in abstentia.

25 JUDGE CHAPPELL: Apparently it's not the New

1 Orleans pronunciation.

2 MR. EISENSTAT: I wouldn't know that either,
3 Your Honor.

4 THE WITNESS: It's the Philadelphia Jewish
5 pronunciation.

6 BY MR. EISENSTAT:

7 Q. Do you recall Judge DuBois telling you at that
8 Markman hearing on that Thursday that he did not want
9 to know what the terms were of any settlement that you
10 reached with ESI?

11 A. No, I certainly don't recall that. And I would
12 hasten to add, Mr. Eisenstat, that what Judge DuBois
13 said on the record and what he said off the record were
14 often not entirely consistent.

15 MR. EISENSTAT: May I approach, Your Honor?

16 JUDGE CHAPPELL: Yes, you may.

17 MR. EISENSTAT: This is a document that's been
18 marked CX 1673 for identification. It is not in
19 evidence, Your Honor.

20 JUDGE CHAPPELL: Thank you.

21 BY MR. EISENSTAT:

22 Q. This is the -- our understanding is this is the
23 transcript of the second day of the Markman hearing,
24 the January 22nd, 1998.

25 Let me direct your attention to page 126 of the

1 document. Toward the -- about two-thirds down the
2 page, the document reads:

3 "THE COURT: All right, what we will do is
4 recess now. We will have no more evidence. What we
5 will have is presentation of the closing arguments.
6 Before that we will get the exhibits in order. You
7 have got a 2:00. Is that scheduled for 2:00?

8 "MR. HERMAN: Yes, Your Honor.

9 "THE COURT: A 2:00 settlement conference
10 before Judge Reuter."

11 Do you see that section?

12 A. Yes, I do.

13 Q. Does that refresh your recollection about
14 whether there were to be closing arguments on the
15 Markman hearing?

16 A. I don't know if there were closing arguments or
17 not, sir, no.

18 Q. And on the next page, 127, the last paragraph
19 on that page, the judge is talking:

20 "I want to hear closing arguments. I'll have
21 some questions. They will not be brief. We're not
22 going to have five or ten minutes. I'm going to limit
23 you -- I'm not going to limit you, and I think I'll
24 cancel or postpone my 4:45 conference. I don't know
25 how long you will be downstairs with Judge Reuter. I

1 want you to stay as long as you think you have to stay,
2 and I'll remain this evening as long as it takes to
3 finish this matter."

4 Do you see that section?

5 A. I do, sir, yes.

6 Q. Does that refresh your recollection at all
7 about whether or not there were closing arguments?

8 A. Mr. Eisenstat, I don't know. I was focused on
9 two things, the fact that Judge DuBois wanted us to go
10 see Judge Reuter and settle the case and my inability
11 to go home to attend to a family problem. I don't
12 recall.

13 Q. Okay. Turn to the next page of the transcript,
14 if you will. First of all, near the top of the page,
15 do you see where the court recesses at 12:55 p.m.?

16 A. I see where the transcript says that, yes.

17 Q. And that's on page 128. And then underneath
18 that it reads "Afternoon Session."

19 Do you see that?

20 A. I do, sir.

21 Q. And the document reads, it says:

22 "THE COURT: Well, we're back on the record.
23 Counsel and client representatives have spent I guess
24 somewhere around -- 2:00 until around -- until about
25 5:30 with Judge Reuter and reported to me that they

1 were much closer with respect to a resolution of this
2 case than they were this morning, and that's heartening
3 to the Court, and I encourage that effort and want you
4 to continue to pursue the question of settlement. A
5 further settlement conference has been scheduled before
6 Judge Reuter for 2:30 tomorrow. Counsel have asked
7 that I defer closing arguments. They would much rather
8 talk and focus on the question of settlement, and I
9 agree with that completely."

10 Do you see that section?

11 A. I do, sir.

12 Q. Does that refresh your recollection at all
13 about asking the judge to defer closing arguments so
14 you could meet with Judge Reuter on the settlement?

15 A. I -- it does not. In fact, I have a very
16 different memory of what happened. As I said, Judge
17 DuBois, particularly when it came to settlement, often
18 said one thing on the record and another thing
19 privately in chambers.

20 Q. Let's turn to page 138 of the transcript, and
21 138 of the transcript is a section that says:

22 "THE COURT: That's it, done. We are not going
23 to do any more this evening unless counsel have
24 anything they wish to call to my attention.

25 "MR. HERMAN: We have nothing, Your Honor. We

1 very much appreciate the Court's indulgence and
2 patience.

3 "THE COURT: Fine, I thank you for that.

4 "MR. HELLER: Yes, thank you, Your Honor, we
5 have nothing.

6 "THE COURT: You can repay the court's
7 indulgence and patience by compromising on whatever
8 differences remain between you and getting this case
9 settled. I want to know none of the details of the
10 settlement. I only urge that you do whatever you think
11 appropriate, knowing full well that the Court, like the
12 two juries that we heard about in chambers, is not --
13 is just not predictable."

14 Do you see that section?

15 A. Yes, I do.

16 Q. Does that refresh your recollection at all
17 about the judge telling you that he did not want to
18 know the details of any settlement?

19 A. I have no doubt whatsoever that Judge DuBois
20 made that statement on the record.

21 Q. And you think he said something differently off
22 the record?

23 A. I think he didn't address that one way or the
24 other off the record. He expressed a very different
25 tone and attitude in chambers to counsel than he did on

1 the record when there was no transcription and no
2 stenographer.

3 Q. And the judge continues talking, and on page
4 140, near the top of the page, he says:

5 "And what I plan to do, unless you settle the
6 case -- and I want you to report to me if -- we don't
7 settle the case, I want to conclude the Markman hearing
8 and closing arguments tomorrow. I start a trial on
9 Monday, and I don't want to put it off. The
10 alternative would be to do it on Saturday. I'll be in
11 on Saturday, but I don't know if that's a better
12 alternative than doing it tomorrow. If it runs late,
13 then the only one who suffers is the person to whom I
14 report when I leave chambers, and she'll have to go to
15 orchestra alone, but I would rather do it tomorrow. If
16 Saturday is better for you, I'll consider that. Next
17 week is out.

18 "MR. HERMAN: Tomorrow will be better for me,
19 Your Honor."

20 Do you see that part?

21 A. I do.

22 Q. And you said you did have some recollection
23 about having it --

24 A. I said now that you mentioned it, that rang a
25 bell, and, in fact, it does ring a bell, yes.

1 Q. When Schering sued Upsher, Schering sued for --
2 excuse me, when Schering sued ESI, I misspoke, Schering
3 sued for damages as well as injunctive relief, did they
4 not?

5 A. Without reviewing the complaint, I can't be
6 certain. I wouldn't be surprised, but I can't recall
7 for certain without looking at the complaint.

8 Q. Do you still have your binder in front of you?

9 A. Yes, I do, sir.

10 Q. I believe tab 1 is the complaint. Is that
11 correct?

12 A. Yes.

13 Q. Could you look at that and figure out if you
14 sued for damages as well as injunctive relief?

15 A. I'd be happy to. (Document review.) We sought
16 costs and reasonable attorneys' fees.

17 Q. Nothing else?

18 A. It doesn't appear so. By the way, I should
19 tell you, Mr. Eisenstat, at this stage of the case, I
20 was not involved in the case at all.

21 Q. Do you recall hiring an expert economist in
22 that case?

23 A. I don't, sir, no.

24 Q. Do you recall a man named -- let's see if I can
25 find the name -- Jerry Hausman?

1 A. Oh, yes, that does -- yes, that does ring a
2 bell. My partner Mr. Weinstein talked to him at one
3 point.

4 Q. He did more than just talk to him, didn't he?

5 A. I don't know. I wasn't involved in that aspect
6 of the case. I don't know, sir.

7 Q. You weren't involved at all in that aspect?

8 A. I -- I knew about it. I also must say, I'm
9 getting a little bit uncomfortable on privilege issues
10 here, because all I can relate here are conversations
11 that I had with Mr. Weinstein that would inextricably
12 involve my talking about my mental impressions and
13 processes.

14 Q. And you won't discuss your mental impressions
15 and processes?

16 MR. NIELDS: I will interpose an objection,
17 Your Honor, to questions to Mr. Herman about his
18 conversations with his partners about the case.

19 JUDGE CHAPPELL: I don't think the question
20 called for a mental impression or process, so I'm
21 overruling it at this time.

22 BY MR. EISENSTAT:

23 Q. Were you aware -- first of all, do you know who
24 Jerry Hausman is?

25 A. He's an economist. I can't recall if he's at

1 MIT or at Harvard. I think I may have met him once.

2 Q. Did he do an expert report for Schering in this
3 case?

4 A. He may have. I just don't know, sir.

5 Q. When the parties settled, that is, Schering and
6 ESI settled their case, was ESI on the market with a
7 generic product?

8 A. Well, they had capsules called Micro-K 8 and
9 Micro-K 10.

10 Q. They did not have a generic product -- were
11 they on the market with a generic product that you
12 alleged infringed a Schering patent?

13 A. No. I recall there was some suggestion that
14 they were actually making an infringing product or at
15 least components of an infringing product overseas,
16 perhaps in Egypt, but I don't recall the details about
17 that.

18 Q. They weren't selling a generic product or
19 generic version of the K-Dur 20 product that infringed
20 the patent, they weren't selling that in the United
21 States?

22 A. Not in the United States, and actually, now
23 that you mention it, Mr. Eisenstat, that rings a bell
24 that it may be -- and I can't be certain of that,
25 because this was a very small part of the case for a

1 very small -- very short period of time, that the
2 economist, Dr. -- I can't recall his name, but he may
3 have been retained in connection with the possibility
4 of sales or products being made in Egypt, but I can't
5 be sure of that. I just -- I don't recall for sure.

6 Q. Do you recall if you ever saw a copy of his
7 report?

8 A. I don't recall seeing one. I'm not even
9 certain there was a report. If you tell me there was,
10 I suppose there was, but I don't recall seeing it, no.

11 Q. At the time of the settlement between ESI and
12 Schering, ESI was still blocked by the 30-month
13 statutory stay under the Hatch-Waxman Act, were they
14 not?

15 A. That's asking for a legal --

16 MR. NIELDS: Your Honor, I object. That's
17 asking for a legal opinion on an issue that Mr. Herman
18 has not been shown to have any expertise. We've just
19 had a witness testify that there was substantial
20 uncertainty at that point in time. I don't see how --
21 what the point of asking Mr. Herman this question is.
22 Their witness said there was substantial uncertainty.

23 MR. EISENSTAT: That was about the 180-day --

24 MR. NIELDS: Oh, I'm sorry, Your Honor, I
25 misheard, misunderstood. I withdraw my objection.

1 JUDGE CHAPPELL: Thank you. The witness is
2 instructed to answer.

3 THE WITNESS: Yes, I believe that the 30-month
4 statutory stay under the Hatch-Waxman Act at the time
5 precluded ESI Lederle from introducing their generic
6 product if they had one that could be introduced, which
7 they didn't, because they didn't have FDA approval
8 anyway.

9 BY MR. EISENSTAT:

10 Q. Do you know when the 30-month stay would have
11 expired?

12 A. No, sir, I don't.

13 Q. Do you know when it was counted from?

14 A. It was -- as I recall -- I haven't looked at
15 that aspect of the Hatch-Waxman Act for a while, but as
16 I recall, it begins to run on the date on which the
17 ANDA is filed -- excuse me -- yeah, it's the date on
18 which the Paragraph IV certification is filed, I
19 believe. I haven't thought about that in a while, but
20 that's my best memory.

21 Q. And that would have been sometime around the
22 end of 1995?

23 A. It would have been roughly 45 days prior to the
24 filing of the complaint and lawsuit, because under
25 Hatch-Waxman, to invoke the statutory stay, a lawsuit

1 has to be filed within 45 days, I believe.

2 Q. And the complaint was filed when?

3 A. Was it September? I -- I think it was
4 September. No, I still have that wrong. February
5 1996.

6 Q. So, the 30 months would run from approximately
7 45 days prior to that?

8 A. Actually, Mr. Eisenstat, now that I think about
9 it, I think it runs 30 months from the date on which
10 the complaint is filed, but I -- without looking at the
11 statute, I can't be certain. I'd want to look at the
12 statute.

13 Q. So, it would be somewhere between 45 days
14 before to the date of the complaint, and then you have
15 30 months where they would be precluded from entering
16 the market. Is that right?

17 A. I believe that's right. I would want to look
18 at the statute to be certain. I haven't looked at the
19 Hatch-Waxman Act in a long time, and in this respect I
20 haven't looked at it in several years actually.

21 Q. So, if Schering did not settle its patent
22 litigation with ESI and reached that agreement in
23 principle in January 1998, ESI was not free to go on
24 the market, were they?

25 A. Well, I haven't done the math to count the 30

1 months, but if the -- if the 30 months hadn't run and
2 the Court hadn't ruled that -- this isn't precisely the
3 language of the statute, but that the -- the case were
4 not being prosecuted with due diligence, then yes, they
5 would not be able to market an approved product if they
6 had one.

7 Q. And you were prosecuting that case with due
8 diligence, weren't you?

9 A. Oh, yes, absolutely.

10 Q. And after the expiration of the 30-month
11 stay -- now, before your settlement with ESI, you had
12 already settled with Upsher-Smith, right?

13 A. Yes.

14 Q. After the expiration of the 30-month stay, if
15 Upsher-Smith did have the statutory 180-day exclusivity
16 period, then ESI still couldn't come to market until
17 180 days after Upsher-Smith. Is that correct?

18 A. Well, I -- at the time, I didn't think about
19 the 180-day exclusivity period, but if you're asking me
20 now if there's a 180-day exclusivity period, do they
21 have to wait 180 days, the answer is, of course, yes.

22 Q. And Upsher-Smith you knew from your settlement
23 with Upsher-Smith wasn't going to come on the market
24 until September 2001, right?

25 A. I haven't looked at that settlement agreement

1 in a long time, but if that's what it said, that's what
2 it said, sir. I don't recall.

3 Q. What happens when you don't end the case, the
4 case is still ongoing, and a 30-month stay expires and
5 the generic's no longer precluded from marketing the
6 drug by the 30-month stay and there would be no -- if
7 there were no 180-day exclusivity period to keep the
8 generic off the market, is the generic company free to
9 enter the market while the patent litigation is
10 ongoing?

11 MR. CURRAN: Objection, Your Honor, calls for
12 expert testimony.

13 MR. NIELDS: Same objection, Your Honor.

14 JUDGE CHAPPELL: Response?

15 MR. EISENSTAT: I'm just asking him about
16 the -- he was talking about settling the case, and I'm
17 just asking him about the consequences of not settling
18 and what are the realistic consequences to his client,
19 and we now know that they weren't damaged immediately
20 because of the Hatch-Waxman. If Upsher-Smith had the
21 180 days, they wouldn't be damaged, because they still
22 couldn't -- ESI still couldn't get on the market. Now
23 I'm asking him what happens if we don't have that 180
24 days, what is -- would he be injured then?

25 JUDGE CHAPPELL: I am going to overrule the

1 objection and allow it just to establish the extent of
2 the witness' knowledge in this area, not for an expert
3 opinion.

4 MR. EISENSTAT: Thank you, Your Honor.

5 THE WITNESS: I'm sorry, sir, could you repeat
6 the question?

7 MR. EISENSTAT: Let me try.

8 JUDGE CHAPPELL: Or we can have the reporter
9 read it.

10 MR. EISENSTAT: Okay. Could you please read
11 back the question?

12 (The record was read as follows:)

13 "QUESTION: What happens when you don't end the
14 case, the case is still ongoing, and a 30-month stay
15 expires and the generic's no longer precluded from
16 marketing the drug by the 30-month stay and there would
17 be no -- if there were no 180-day exclusivity period to
18 keep the generic off the market, is the generic company
19 free to enter the market while the patent litigation is
20 ongoing?"

21 THE WITNESS: The answer to that is a very
22 decisive maybe. The -- I must tell you, I've never
23 myself encountered that situation, and I'm not talking
24 from firsthand knowledge, but as I think now through
25 the possibilities, yes, it's true the 30-month stay

1 wouldn't be in place, and in theory, at the risk of
2 accumulating a damages claim, a company could go on the
3 market on the one hand.

4 On the other hand, even upon the expiration of
5 the 30-month stay, the patent holder would be free to
6 seek an injunction under the -- under the United States
7 Patent Act, and I think it is impossible to predict in
8 advance how that would all play out. I just don't
9 know.

10 BY MR. EISENSTAT:

11 Q. So, the patent holder has a right to seek an
12 injunction to further preclude the generic?

13 A. Sitting here today, I can't think of any reason
14 why the patent holder wouldn't. I don't know that any
15 court has ever spoken to the issue. I'm not aware that
16 any court has. I myself have never encountered it.

17 Q. If the generic were to enter the market before
18 the patent suit was resolved and there was no
19 injunction and they were on the market, would Schering
20 be allowed to seek damages from that generic company if
21 they did eventually win the patent case?

22 A. When an infringing product is introduced into
23 the market and a court finds it to have infringed, the
24 patent holder's entitled to damages.

25 Q. So, Schering -- if ESI's case had never been

1 settled and it just kept going and eventually ESI did
2 enter the market and Schering eventually won their
3 patent case, could Schering have then sought damages?

4 A. Yes.

5 Q. Have you ever encountered -- let me start
6 again.

7 In your practice, you have -- have you
8 represented other drug manufacturers besides Schering?

9 A. Yes.

10 Q. Have you done other patent litigation with
11 them?

12 A. Yes.

13 Q. Have you ever encountered a generic
14 manufacturer who sought to enter the market after the
15 30-month stay was up if the patent litigation was still
16 ongoing?

17 A. No, as I said, sir, I've never encountered that
18 situation.

19 Q. Do you recall having your deposition taken in
20 this case?

21 A. Yes, I do.

22 Q. And do you recall at your deposition you were
23 instructed not to answer any questions that revealed
24 your mental impressions?

25 A. I don't recall that particular statement with

1 certainty, but I would be surprised if Mr. Nields
2 didn't make that statement.

3 Q. Let me show you the statement that Mr. Nields
4 did make at your deposition. This is from page 7 of
5 your deposition, line 3:

6 "MR. NIELDS: I would like to just make a brief
7 statement at the outset of the deposition. And I think
8 you will bring out in a moment, Mr. Herman is an
9 attorney with the law firm of Covington & Burling, and
10 was acting as an attorney representing Schering/Key in
11 the two patent litigations that, the settlement of
12 which is involved in this case.

13 "And he has been designated a witness by
14 Schering because he had conversations with the
15 adversary in the ESI litigation and also with the
16 magistrate judge. And those conversations we believe
17 relevant to the case.

18 "But if questions stray into areas such as
19 privileged areas, such as conversations with his client
20 or into his mental impressions, then we will object and
21 I will be directing him not to answer."

22 Do you recall that statement?

23 A. I recall the substance of the statement. I
24 don't recall the precise words, yes.

25 Q. And do you recall that you did, in fact, follow

1 your counsel's instructions?

2 A. Oh, that I recall quite well, yes. Of course I
3 did.

4 Q. And you did not give any testimony about your
5 mental impressions?

6 A. When Mr. Nields directed me not to testify, I
7 didn't testify, yes.

8 Q. And you didn't testify about -- you declined to
9 testify about conversations where you told your client
10 something?

11 A. If it -- if the communication with my client
12 was privileged, that's true. Not everything that a
13 lawyer tells his or her client is privileged.

14 Q. You're right, and I misspoke, you're absolutely
15 right. I meant to limit it to those situations where
16 you were outside of third parties, outside of the
17 hearing range of third parties, and it was a privileged
18 conversation, then you declined to answer those?

19 A. If it was a conversation that entailed a
20 communication in the course of providing legal advice
21 and consequently was privileged in that it was never
22 revealed to third parties, if I did so testify, it was
23 in error, but I don't recall so testifying.

24 Q. You don't recall doing that, do you?

25 A. No, I don't, sir.

1 Q. And that would be true with respect to what you
2 told your clients as well as what your clients told you
3 in those conversations?

4 A. Well, I could repeat my answer, sir. I don't
5 recall testifying as to any privileged conversations
6 that I had with my client or that my client had with
7 me.

8 MR. EISENSTAT: May I have just a moment, Your
9 Honor?

10 JUDGE CHAPPELL: Yes.

11 (Pause in the proceedings.)

12 MR. EISENSTAT: No further questions, Your
13 Honor.

14 JUDGE CHAPPELL: Thank you.
15 Redirect?

16 MR. NIELDS: No, Your Honor.

17 JUDGE CHAPPELL: Thank you, Mr. Herman. You're
18 free to go.

19 THE WITNESS: Thank you, Your Honor.

20 JUDGE CHAPPELL: Call your next witness,
21 please.

22 MR. NIELDS: Your Honor, the next witness is
23 Mr. Rule. He is not available tomorrow morning. My
24 direct of him is relatively brief, but if the cross
25 were to go over, he would not be available tomorrow

1 morning. The other witness that we were going to call
2 this afternoon, Mr. Hoffman I was asked -- I was asked
3 not to call this afternoon in order to accommodate
4 counsel. So, he is not available, and my question is
5 do we want to go ahead with Mr. Rule under those
6 circumstances? I don't want to prejudice the other
7 side.

8 MS. BOKAT: Your Honor, I would just add to Mr.
9 Nields' point on Mr. Hoffman's testimony. Mr. Nields
10 did make an accommodation because our counsel who was
11 going to cross examine or will cross examine Mr.
12 Hoffman had a medical appointment this afternoon.

13 MR. CURRAN: Just in case you want to hear from
14 me, Your Honor, I don't intend to ask --

15 JUDGE CHAPPELL: If you stand up, I'll hear
16 from you.

17 MR. CURRAN: I appreciate it.

18 JUDGE CHAPPELL: Okay.

19 MR. CURRAN: I don't intend to ask Mr. Rule any
20 questions, but I'm available to stay here as long as
21 necessary this evening to accommodate the witness and
22 other counsel.

23 JUDGE CHAPPELL: That's become a slippery
24 slope.

25 What about filler time if he's not available in

1 the morning? Are you going to have deposition
2 excerpts?

3 MR. NIELDS: Well, tomorrow morning, Your
4 Honor, we've got other -- no, we don't have those. We
5 have other witnesses, and Mr. Rule could testify at the
6 end of the day tomorrow, and --

7 JUDGE CHAPPELL: So, you're assuming then that
8 the cross is taken out of order, that you have someone
9 plugged in before the cross is finished if it's not
10 finished today?

11 MR. NIELDS: There are three options, Your
12 Honor. One is to do Mr. Rule now and finish him today,
13 whatever that takes. Again, I don't know how long the
14 cross is going to be, but the direct is pretty brief.
15 The second option would be to simply start with our
16 witnesses tomorrow and have Mr. Rule testify as the
17 third witness tomorrow. And the other option would be
18 to start him and break at 5:30 and interrupt his cross,
19 but that I wouldn't obviously suggest without complaint
20 counsel's agreement.

21 JUDGE CHAPPELL: One other option, the parties
22 could ask for a recess and settle the case, but since
23 that's not going to happen, let's go ahead and call
24 your next witness. Let's proceed.

25 Raise your right hand, please.

1 Whereupon--

2 CHARLES F. "RICK" RULE

3 a witness, called for examination, having been first
4 duly sworn, was examined and testified as follows:

5 JUDGE CHAPPELL: Have a seat.

6 State your full name for the record, please.

7 THE WITNESS: My name is Charles F. "Rick"

8 Rule.

9 DIRECT EXAMINATION

10 BY MR. NIELDS:

11 Q. Mr. Rule, what is your occupation?

12 A. I'm a lawyer.

13 Q. And do you specialize in any particular area of
14 law?

15 A. I do, antitrust law.

16 Q. And how long have you been practicing antitrust
17 law?

18 A. Pretty much since I graduated law school in
19 1981.

20 Q. What's your educational background?

21 A. I have a BA from Vanderbilt University and a JD
22 from the University of Chicago Law School.

23 Q. When did you get your JD?

24 A. 1980.

25 Q. Could you describe your job history since you

1 graduated from law school?

2 A. I clerked in the District of Columbia for --
3 and Chief Judge Daniel Friedman of the old U.S. Court
4 of Claims. After that, in the fall of 1982, I became
5 the Special Assistant to the then Assistant Attorney
6 General in terms of the Antitrust Division, Bill
7 Baxter. I served as his Special Assistant until
8 January of 1984 when I became a Deputy Assistant
9 Attorney General for Policy Planning and Legislation
10 under the then Assistant Attorney General Paul McGrath.

11 I held that position until 1985. When Doug
12 Ginsburg, who had been the Deputy Assistant for
13 Regulatory Affairs, left, I assumed those
14 responsibilities, and then for about six months in
15 1985, after Paul McGrath left, the Assistant Attorney
16 General, I became the Acting Assistant Attorney General
17 in charge of the Antitrust Division.

18 When Doug Ginsberg came back to replace --
19 become the confirmed head of the Division, Assistant
20 Attorney General, I then became the Principal Deputy
21 Assistant Attorney General in the Antitrust Division
22 and served in that position until late 1986, when Doug
23 Ginsburg became a judge on the Court of Appeals for the
24 District of Columbia Circuit. At that point, I became
25 the acting head of the Division and in 1987 was

1 nominated and confirmed by the Senate as the Assistant
2 Attorney General in charge of the Antitrust Division, a
3 position I held until May of 1989, when I became a
4 partner at the Washington law firm of Covington &
5 Burling.

6 I left Covington in January of 2001 and became
7 a partner and head of the antitrust department at
8 Fried, Frank, Harris, Shriver & Jacobson, and that is
9 where I am today.

10 Q. Now, I take it, then, you were a partner at
11 Covington & Burling in 1997?

12 A. I was.

13 Q. And were you involved in mediation discussions
14 involving a case called Key Pharmaceuticals against
15 ESI?

16 A. I had two conversations, to my recollection, in
17 connection with settlement efforts involving parties
18 other than Schering in that case, yes.

19 Q. And was Schering your client?

20 A. Yes, it was.

21 Q. Now, you said you had two such discussions.
22 Was one directly with ESI's counsel and the other at
23 mediation with Judge Reuter?

24 A. Yes.

25 Q. Let's move, for sake of brevity, to the

1 mediation session.

2 A. Okay.

3 Q. Do you remember -- well, first of all, where
4 was it? Where was the mediation discussion?

5 A. My recollection is that it was in the Federal
6 Courthouse in Philadelphia, Pennsylvania in the
7 courtroom and then in the chambers of Magistrate Judge
8 Reuter.

9 Q. And do you remember when it was?

10 A. Not exactly, but I believe it was in the late
11 summer of 1997.

12 Q. And who was there?

13 A. Again, I'm not sure I knew at the time the
14 identity of everybody who was present, and I certainly
15 don't recall that now. I do know that Tony Herman, one
16 of my partners at Covington & Burling, was there. I
17 recall Susan Lee, who was an in-house attorney at
18 Schering-Plough, was there. Ray Kapur, who was a
19 business executive affiliated with Schering-Plough, was
20 there. There were a number of attorneys and perhaps
21 business folk on the other side representing ESI, and,
22 of course, Judge Reuter was there as well.

23 Q. And how long did this mediation event last?

24 A. I, because of traffic complications, missed the
25 train up, so I drove up and got there a little late.

1 As I recall, the session was to begin at 10:00. I
2 think I got there at 10:30 or 11:00, something like
3 that. My recollection is that there was a lunch break,
4 and the session ended sometime in the late afternoon
5 around 4:00 or so.

6 Q. And at the beginning, where was everyone?

7 A. Again, my recollection is that when I arrived,
8 there was a session going on that involved both parties
9 in front of the judge in his courtroom.

10 Q. And can you describe what -- well, did there
11 come a time when you participated in those discussions
12 in the courtroom?

13 A. Yes, I -- there were -- you know, my
14 recollection is there were a number of issues discussed
15 that were not particularly of interest or of note for
16 me that had to do with discovery and other sorts of
17 issues and generally the mediation process, but at some
18 point during that session in the judge's courtroom, I
19 do recall that I got up to make a -- say a few words
20 about the -- about antitrust concerns with what was
21 explained as ESI's proposal for settlement.

22 Q. And what was the proposal that you were
23 responding to?

24 A. As I understood it, ESI was suggesting that the
25 case could be settled, and they would stay off the

1 market in exchange for a large sum of money that would
2 be calculated on the basis of the profits that Schering
3 stood to lose if ESI entered the market with a generic
4 equivalent to K-Dur.

5 Q. Now, did there come a time when you were no
6 longer in the courtroom but rather in chambers?

7 A. Yes, at some point during the day, and my
8 recollection is this was during the afternoon, the
9 judge essentially asked the two parties to separate.
10 The Schering-Plough contingent went to the judge's
11 chambers. I don't know exactly where the ESI folks --
12 they may have stayed in the courtroom. And the judge
13 then shuttled back and forth between the two groups.

14 Q. And did there come a time when you were in
15 chambers with Judge Reuter when you and he had a
16 conversation about antitrust concerns regarding the
17 settlement proposal of ESI?

18 A. Yes, yes.

19 Q. And what led to that?

20 A. It's my recollection that the judge was
21 responding to the comments I believe that I had made in
22 the courtroom about the antitrust issues surrounding
23 the ESI proposal and essentially was raising a
24 question --

25 Q. Could I ask you to stop, because Mr. Eisenstat

1 has stood up.

2 MR. EISENSTAT: Objection, Your Honor, again
3 with respect to the hearsay aspect of what the judge
4 was saying. We just had a witness on the stand who
5 explained that the one judge said one thing in chambers
6 and another thing on the record, and I think that
7 indicates that we have a very big problem with the
8 reliability of evidence about what a judge says, and I
9 would object on the hearsay basis.

10 JUDGE CHAPPELL: Well, as I recall, Mr.
11 Eisenstat, none of that was submitted to the Court or
12 the record for the truth of the matter, which should
13 alleviate your concern in that regard.

14 Response?

15 MR. NIELDS: I agree, Your Honor. These are
16 very -- these are conversations not offered for the
17 truth of the matter asserted, and they are very
18 important to our defense, Your Honor. We regard it as
19 extremely relevant that antitrust issues were shared,
20 concerns were shared by Schering with Judge Reuter
21 before the time when the settlement was entered into at
22 his urging. These are verbal acts, Your Honor.

23 JUDGE CHAPPELL: If he's not submitting it for
24 the truth of the matter asserted, then it's not hearsay
25 under even the federal rule.

1 MR. EISENSTAT: Well, Your Honor, I would
2 submit that what they're really doing is submitting the
3 statements of the judge in order to prove that the
4 judge then approved this agreement between the two
5 parties, somehow blessing it under the antitrust laws,
6 and it's the statements themselves that are in question
7 here, and as I say, we have had testimony where a judge
8 says one thing in one context and another in another
9 context, and I don't think we can even give veracity
10 that the judge had any intention of following through
11 with what he said, so that the conclusions they want to
12 draw, that they discussed this with the judge first and
13 then the judge looked at the settlement and said it was
14 all right, I don't think we can draw those conclusions
15 from this testimony.

16 JUDGE CHAPPELL: I haven't seen anybody offer
17 the conclusion that that's -- that the judge did
18 anything for that reason. I haven't -- I haven't heard
19 that. Have you?

20 MR. EISENSTAT: I think if you -- when I read
21 their papers and their brief, I think they're going to
22 argue that the judge looked at this and approved it and
23 somehow this takes it out of the per se category and/or
24 rule of reason analysis.

25 JUDGE CHAPPELL: Well, if counsel who is

1 questioning the witness represents that it's not
2 offered for the truth of the matter, then I'm
3 overruling your hearsay objection.

4 You may proceed.

5 BY MR. NIELDS:

6 Q. Mr. Rule, I think we stopped you in the middle
7 of an answer, and I think it was what led to the
8 discussion that you and Judge Reuter had on the subject
9 of antitrust concerns of Schering.

10 A. Okay, yeah, my recollection is that the judge
11 in -- I recall in response to what I had said in his
12 courtroom essentially was asking what is the relevance
13 of antitrust -- why is there an antitrust lawyer here
14 in this mediation, and I recall explaining to the judge
15 that notwithstanding that there was a judge involved in
16 the mediation effort and that it was aimed at a
17 settlement, the simple fact -- I explained to the judge
18 it was my understanding of the law that the simple fact
19 that there was --

20 MR. EISENSTAT: Objection, Your Honor. His
21 understanding of the law, the -- we're getting into
22 mental impressions now, and I believe the ruling was we
23 weren't allowed to get into mental impressions.

24 MR. NIELDS: Your Honor --

25 JUDGE CHAPPELL: Well, for one thing, the

1 answer is not responsive to the question you asked.
2 You didn't ask him about what his opinions were about
3 the law or what his understanding was of the law.

4 MR. NIELDS: That's correct, Your Honor, and
5 let's -- let's see if I can reframe it and focus it.

6 BY MR. NIELDS:

7 Q. Mr. Rule --

8 JUDGE CHAPPELL: So, I'm sustaining it in that
9 regard.

10 MR. NIELDS: Okay.

11 BY MR. NIELDS:

12 Q. I believe this is what the witness is trying to
13 do, but let's just make it clear. Could you recount
14 the -- what was said by you to Judge Reuter and what
15 was said by Judge Reuter to you, or if it's the other
16 way around, what was said by Judge Reuter to you and
17 then what was said by you to Judge Reuter, as best you
18 can recall?

19 A. Yes, and that is what I was attempting to do.
20 I was explaining to the judge the law, and again, being
21 the one who was explaining it, I was explaining it
22 based on my understanding, and that's what I told him,
23 and essentially said to the judge, as I recall, that
24 the fact that it was a judicially administered
25 mediation and that it might result in a settlement was

1 not sufficient to give the settlement Noerr-Pennington
2 protection immunizing it under the antitrust laws.

3 But I went on to explain to the judge that the
4 law did and does in effect give deference to a -- to a
5 judicially administered settlement and presumes that a
6 judge in entering or administering a settlement is
7 acting in the public interest and therefore would not
8 approve a per se violation and that the law recognized
9 a value in settling litigation.

10 Having said that to the judge, I went on to
11 indicate that notwithstanding that deference, that I --
12 that the law gave to settlements, that -- and therefore
13 afforded settlements per se -- or rule of reason
14 treatment, that I was concerned about the nature of the
15 ESI proposal, because the ESI proposal, as I had heard
16 it described in the -- in the courtroom, essentially
17 would be a payment of money by Schering-Plough, as I
18 recall the discussion, a figure that was in the high
19 eight, low nine numbers, and which it was purported was
20 a -- based on the amount of profits that
21 Schering-Plough stood to lose if ESI came into the
22 market as competitor.

23 And I indicated to the judge that I felt that
24 that kind of settlement looked like a -- or certainly
25 potentially could look like a payment by one

1 competitor, a part of its profits, which might be
2 viewed as super-competitive profits, to another
3 potential competitor to keep that competitor out of the
4 marketplace, and I explained to the judge that I
5 thought that raised antitrust issues.

6 Q. And what happened next?

7 A. At some point the judge left the -- his
8 chambers and went back to talk to the ESI contingent
9 and came back with a -- you know, some sort of trade
10 publication or something. I'm not sure whether he
11 actually showed it to me or just sort of waved it
12 around, indicating that there were, as he put it, that
13 there were other settlements that ESI had called to his
14 attention that involved the same kind of payment of
15 money in order to keep a potential generic competitor
16 off the market, and the one that I recall being
17 referred to was a settlement between Bayer and Barr.

18 Q. Did you respond to that?

19 A. I did. I told the judge, as I recall it, that
20 I was aware of the fact that there had been other such
21 settlements, that my view was that simply because there
22 were other such settlements and the fact that they were
23 on the public record, that didn't mean that they were
24 lawful under the antitrust laws or that the parties to
25 those would not be subject to investigation or

1 scrutiny, so I did not view -- I told the judge I did
2 not view the fact that there were other such
3 settlements as being of any great relevance to
4 Schering-Plough's evaluation or willingness to enter
5 into what ESI was proposing.

6 Q. Was there any further discussion between you
7 and Judge Reuter on the subject of the payments?

8 A. There was. The judge pressed, as I recall it,
9 to some extent on the payment issue, and I recall
10 telling the judge that I -- you know, while there were
11 concerns with a payment of money as it had been
12 proposed by ESI, that that did not necessarily in my
13 view, I told the judge, mean that one -- that parties
14 couldn't settle patent litigation even with a monetary
15 payment.

16 I recall telling him that, you know, there
17 could be payment for attorneys' fees, there could be a
18 separate, stand-alone, justifiable agreement between
19 the parties, like a co-promote or a licensing in of
20 technology that involved a payment of money. So, I
21 indicated to the judge that I thought there were bases
22 under which there could be a payment of money, but what
23 was particularly troubling about ESI's proposal was the
24 notion of paying some part of Schering's potentially
25 lost profits.

1 I also recall that the discussion or that I
2 made the point that there is a big difference both in
3 terms of size of a payment but also conceptually in
4 basing a monetary value on the incumbent's potential
5 lost profits from a new entry and an amount of money
6 that reflects the amount that the new entrant could
7 expect to earn if they did enter the market, that the
8 fact is that that latter number, the new entrant's
9 expected earnings or revenues, were likely to be much
10 smaller, because the whole point of competition is that
11 when a new entrant comes in, some of the previous
12 profits get competed away as surplus that goes to
13 consumers and that if there were a payment of money
14 that it would, I thought, be more defensible if it were
15 based on the amount of expected revenues that a company
16 like ESI could expect to earn if it entered the market.

17 Q. At the end of this session, was there any
18 agreement to settle or any agreement on Schering's part
19 to pay anything?

20 A. No, my recollection is Schering made it pretty
21 clear that based on their view of the case, based on
22 the antitrust issues that had been raised, that they
23 were not prepared to settle on that basis, but it was
24 clear that the judge was urging the parties to continue
25 to talk to try to come to some agreement.

1 MR. NIELDS: Your Honor, I have no further
2 questions of Mr. Rule.

3 JUDGE CHAPPELL: Thank you.

4 Mr. Eisenstat, considering the testimony just
5 given by this witness, is there information which you
6 requested in discovery but were not provided?

7 MR. EISENSTAT: No, Your Honor.

8 JUDGE CHAPPELL: Cross exam?

9 MR. EISENSTAT: Yes, Your Honor.

10 JUDGE CHAPPELL: You may proceed.

11 CROSS EXAMINATION

12 BY MR. EISENSTAT:

13 Q. Good afternoon, Mr. Rule. It's nice to see
14 you.

15 A. It's good to see you, Mr. Eisenstat.

16 Q. Mr. Rule, are you still retained by Schering?

17 A. Except for the purpose of being paid for my
18 time giving this testimony, no.

19 Q. You are being paid for your time for giving
20 this testimony?

21 A. Yes, yes.

22 Q. And were you paid for your time to give your
23 deposition?

24 A. Yes.

25 Q. At the end of your testimony, you testified

1 that you told the judge that there was a big difference
2 in terms of the size of the payment and conceptually
3 the difference between these lost profits versus the
4 amount of expected earnings. Do you recall that?

5 A. Yes, I do.

6 Q. And you said you testified -- you said you
7 explained to the judge that this is -- I'm
8 paraphrasing, of course -- but that this difference can
9 be explained by the fact that when there's new entry,
10 part of the profits gets competed away to consumers'
11 benefit. Is that right?

12 A. Yes, that's correct.

13 Q. Did you explain to the judge that the consumers
14 don't benefit if the generic stays off the market
15 because of the payment for either of these amounts?

16 A. I don't recall discussing that issue, no.

17 Q. I mean, that's true, is it not, that the
18 consumers wouldn't benefit from the competition if the
19 generic stays out regardless of which payment it was?

20 MR. CURRAN: Objection, Your Honor, calls for
21 expert testimony from a fact witness.

22 JUDGE CHAPPELL: It's fair cross examination.
23 Overruled.

24 THE WITNESS: Well, it -- if one assumes away,
25 which in the discussion with the judge I wasn't

1 assuming away, the fact that there was patent
2 litigation and a legitimate patent dispute, the fact of
3 whether or not a company comes in or not and the terms
4 under which it comes in, you know, obviously would
5 depend on the outcome of that patent litigation, but
6 assuming that away and assuming there was no basis for
7 Schering to assert some intellectual property rights to
8 keep a generic out, then yes, one would expect as
9 generics come into the market prices would decline and
10 consumers would benefit.

11 BY MR. EISENSTAT:

12 Q. And if the payments kept the generics off
13 regardless of whether the payments were based on lost
14 profits of the branded company or the expected earnings
15 of the generic, regardless of which those payments were
16 based on, if those payments kept the generic
17 manufacturer off the market, consumers would lose that
18 benefit.

19 A. That assumes that the generic would not --
20 would otherwise be able to come in. If the generic
21 lost the patent suit and was kept out entirely, then
22 obviously consumers wouldn't be made any better off
23 whether or not the generic received money.

24 Q. Okay, but if -- assuming that the generic were
25 free to enter, then --

1 A. Absolutely, as I explained to the judge, if a
2 generic, you know, comes in, there is in effect some
3 transfer of wealth to the consumers and that in the
4 absence of the context of a settlement, that would be a
5 very problematic agreement between two competitors.

6 As I also explained to the judge, when it is in
7 the context of a settlement, the law is pretty clear
8 that the fact that it's within the context of a
9 judicially supervised settlement gives it a deference
10 and a rule of reason treatment, as I understand it, and
11 therefore, you can't really equate a situation where
12 two parties are free to compete and there is no
13 litigation to one where there is litigation.

14 Q. Were you present at the meeting between
15 Schering and ESI in Judge Reuter's office where they
16 reached an agreement in principle to settle the case?

17 A. I was not.

18 Q. Do you know of your own knowledge whether or
19 not there was any judicial supervision of that
20 settlement?

21 A. I do not.

22 Q. When you were appearing before the Magistrate
23 Judge Reuter, had you been retained by the magistrate
24 as a special master?

25 A. I had not.

1 Q. Were you there providing expert testimony?

2 A. I was not. Again, it was not a formal
3 proceeding. It was a mediation settlement, and I was
4 there to present, as Schering's lawyer, the views of
5 Schering on the antitrust issues created or raised by
6 what ESI was proposing.

7 Q. And you weren't neutral at this proceeding; you
8 were representing a client.

9 A. I was definitely representing my client.

10 Q. And the less money Schering had to pay to
11 keep -- to get the ESI settlement, the better off
12 Schering was. Is that fair?

13 A. That's fair.

14 MR. EISENSTAT: Could I have just a moment,
15 Your Honor?

16 JUDGE CHAPPELL: Yes, you may.

17 (Counsel conferring.)

18 MR. EISENSTAT: No more questions, Your Honor.

19 JUDGE CHAPPELL: Anything further?

20 MR. NIELDS: No, Your Honor.

21 JUDGE CHAPPELL: Thank you, Mr. Rule. You're
22 excused.

23 THE WITNESS: Thank you.

24 MS. BOKAT: Your Honor, before we break for the
25 day, and maybe we're not there yet, I just wanted to

1 make a mental note, I've got a -- an exhibit to
2 substitute.

3 JUDGE CHAPPELL: Okay.

4 MS. BOKAT: Is this the time to do it or would
5 you like me to wait?

6 JUDGE CHAPPELL: This is the time. If you wait
7 much longer, we'll all be gone, so --

8 MS. BOKAT: That's why I interjected myself.

9 JUDGE CHAPPELL: Okay.

10 MS. BOKAT: Last evening, when David Narrow was
11 examining Joel Hoffman, he used a visual that was a
12 chronology --

13 JUDGE CHAPPELL: The one with the typo?

14 MS. BOKAT: Right.

15 JUDGE CHAPPELL: Okay.

16 MS. BOKAT: And you had asked for a correction.
17 We have made the correction by striking through the old
18 date, putting in the new one, and I hope we've adjusted
19 the spacing on the time line, so I would like to -- we
20 didn't put the new exhibit number on it. It has the
21 old exhibit number, but I would like to substitute this
22 with the permission of the Court.

23 JUDGE CHAPPELL: Any objection?

24 MR. NIELDS: No objection, Your Honor.

25 MR. CURRAN: No objection, Your Honor.

1 JUDGE CHAPPELL: You may.

2 MS. BOKAT: Thank you, Your Honor.

3 JUDGE CHAPPELL: Anything further before we
4 adjourn for the day?

5 MR. NIELDS: No, Your Honor.

6 JUDGE CHAPPELL: Okay, we will begin at -- we
7 will adjourn until 9:30 in the morning. Good night.

8 (Whereupon, at 5:35 p.m., the hearing was
9 adjourned.)

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1 C E R T I F I C A T I O N O F R E P O R T E R

2 DOCKET/FILE NUMBER: 9297

3 CASE TITLE: SCHERING-PLOUGH/UPSHER-SMITH

4 DATE: FEBRUARY 7, 2002

5

6 I HEREBY CERTIFY that the transcript contained
7 herein is a full and accurate transcript of the notes
8 taken by me at the hearing on the above cause before
9 the FEDERAL TRADE COMMISSION to the best of my
10 knowledge and belief.

11

12 DATED: 2/8/02

13

14

15

16 SUSANNE BERGLING, RMR

17

18 C E R T I F I C A T I O N O F P R O O F R E A D E R

19

20 I HEREBY CERTIFY that I proofread the
21 transcript for accuracy in spelling, hyphenation,
22 punctuation and format.

23

24

25 DIANE QUADE

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